

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES
PRACTICES, AND PRODUCTS
LIABILITY LITIGATION**

MDL No. 16-2738 (MAS)(RLS)

***THIS DOCUMENT RELATES TO
ALL CASES***

**THE PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF
LAW IN OPPOSITION TO JOHNSON & JOHNSON AND LLT
MANAGEMENT LLC'S MOTION TO EXCLUDE PLAINTIFFS'
EXPERTS' ASBESTOS-RELATED OPINIONS**

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EXECUTIVE SUMMARY

The Transmission Electron Microscopy (TEM) methodology used by Dr. William Longo and Dr. Mark Rigler was approved by Chief Judge Wolfson. There is no valid reason to disturb her ruling, and the inquiry into Drs. Longo and Rigler's TEM methodology should end there. But if there is any doubt Chief Judge Wolfson was correct, the White Paper subsequently published in 2021 by the Interagency Working Group on Asbestos in Consumer Products (IWGACP),¹ following a public hearing and the receipt of numerous written submissions by all interested parties, confirms it is an acceptable methodology. Sixty-eight percent (68%) of the samples tested by Plaintiffs' experts were positive for amphibole asbestos. They did not test for chrysotile. The Court should summarily reject any challenge to this testing methodology.

In his Fourth Supplemental Report, Dr. Longo set forth the results of his testing for chrysotile using Polarized Light Microscopy (PLM) and Heavy Liquid Separation (HLS). The use of PLM and HLS together is a new methodology used to identify another type of asbestos, chrysotile, that is being presented to the Court. It is also reliable and generally accepted. The positive findings of chrysotile asbestos in J&J's talcum powder products by Drs. Longo & Rigler are further supported by

¹ **Exhibit 1**, *White Paper: IWGACP Scientific Opinions on Testing Methods for Asbestos in Cosmetic Products Containing Talc* (Dec. 2021), pg. 111.

Johnson & Johnson's ("J&J") own documents, the geological literature, and the testing of other labs as outlined by Drs. Cook and Krekler. It is universally accepted by everyone except J&J that exposure to asbestos can cause ovarian cancer.

INTRODUCTION

For well over 50 years, Defendant Johnson & Johnson has known that the talc it used to make Johnson's Baby Powder ("JBP") contained asbestos. In an April 26, 1973, internal memorandum, one of J&J's executives most familiar with its talc products acknowledged this:

It is our joint conclusion that we should not rely on the "Clean Mine" approach as a protective device for Baby Powder in the Current Asbestos or Asbestos-form controversy. We believe this mine to be very clean; however, we are also confident that fiber forming or fiber type materials could be found. The usefulness of the "Clean Mine" approach for asbestos only is over.²

Later in that memorandum he added:

Our Baby Powder contains talc fragments classifiable as fiber. Occasionally sub-trace quantities of tremolite or actinolite are identifiable (optical Microscope) and these might be classified as asbestos fiber.³

Since the 1960s, J&J and its outside consultants have continued to find asbestos in JBP and its mine sources, including chrysotile and amphibole asbestos, using multiple testing methods, including Polarized Light Microscopy (PLM) and

² J&J Memo from D. R. Petterson to D. D. Johnson (Apr. 26, 1973), attached hereto as **Exhibit 2**.

³ *Id.* at 2.

Transmission Electron Microscopy (TEM).⁴ What J&J's executives acknowledged internally in the 1970s about the presence of asbestos in JBP has now been confirmed by Dr. William Longo and Dr. Mark Rigler using multiple modern and generally accepted scientific testing methodologies.⁵ During the *Daubert* Hearings in 2019, Dr. Longo testified for a full day about using TEM. Notably, Chief Judge Wolfson found his testimony admissible under Federal Rule of Evidence 702. As the 2023 amendments to Rule 702 did not substantively modify the *Daubert* standards, this Court should adopt Chief Judge Wolfson's findings and deny Defendants' motion to exclude Drs. Longo and Rigler's TEM opinions. Since that hearing, Dr. Longo has published some of the results of his testing in a peer reviewed journal, has been asked to testify before Congress and the U.S. Food and Drug Administration about his talc testing, and has had his testimony on the testing of talc for asbestos admitted over J&J's and or other defendants' objections in over a dozen mesothelioma trials⁶

Although Chief Judge Wolfson excluded Dr. Longo's then-existing polarized light microscopy ("PLM") methodology, Dr. Longo has since revised the protocol. As Dr. Longo came to learn, the Colorado School of Mines developed a heavy liquid

⁴ See Hopkins Exhibit 28 (chart of Samples with asbestos), attached as **Exhibit 3**.

⁵ In addition to J&J's own documents, the published literature provides further support for Drs. Longo and Rigler's identification of asbestos in numerous historical samples. This literature and other authoritative references are examined at length in the expert reports of Plaintiffs' geologists, Drs. Cook and Krekeler, which are discussed on pp. 99-104 of this Opposition.

⁶ Since February 2020, every mesothelioma trial against J&J has resulted in a plaintiff's verdict, with the most recent in South Carolina last week.

separation sample preparation method (“HLS”) in the 1970s for J&J, which improved the sensitivity of PLM testing such that it could detect low levels of chrysotile asbestos. As others have done since, Dr. Longo has combined PLM and HLS to detect chrysotile asbestos in JBP at levels below which PLM alone could not. Because the combined PLM/HLS methodology addresses Chief Judge Wolfson’s concerns in excluding the original PLM methodology, the current PLM/HLS methodology satisfies Rule 702’s standards and should be admitted.

J&J’s attacks on Plaintiffs’ other experts who address asbestos issues in their reports—or rely in part on Dr. Longo and Rigler’s work—are similarly without merit. The scientific literature and evidence, including J&J and Imerys Talc America’s (“Imerys”) own documents, fully supports a causal connection between asbestos exposure and ovarian cancer and that the talc deposits in Italy, Vermont, and China used by J&J were contaminated by asbestos.

For all these reasons, Defendants’ motion to exclude Plaintiffs’ experts’ asbestos-related opinions should be denied.

FACTUAL BACKGROUND

I. Drs. William Longo and Mark Rigler are eminently qualified, and their opinions have been accepted by numerous courts.

A. Dr. William E. Longo

Dr. William E. Longo has a Bachelor of Science degree in Microbiology, a Master of Science degree in Engineering, and a Doctorate in Philosophy in Materials

Science, from the University of Florida.⁷ According to Judge Wolfson in the April 27, 2020 *Daubert* Opinion, “[t]here is no dispute that Dr. Longo is qualified to testify as an expert on the issue of whether the subject talc products contain asbestos.”⁸

As the President of MAS, LLC since 1987,⁹ Dr. Longo has studied the content, type, and release of asbestos fibers from asbestos-containing products.¹⁰ As a material scientist, Dr. Longo studies the structure, properties, synthesis, and performance of a wide range of materials.¹¹ He also examines why and how materials behave under various conditions, such as temperature, pressure, stress or exposure to climatic conditions, and how materials are used in every aspect of people’s lives.¹²

Dr. Longo is a member of numerous organizations and professional groups specializing in the testing and analysis of asbestos-containing materials, including the Environmental Protection Agency (EPA) Peer Review Group for the Asbestos Engineering Program, the American Industrial Hygiene Association (AIHA), Materials Research Society, American Society for the Testing of Materials (ASTM), and the American Society of Materials.¹³ Dr. Longo has given numerous lectures on

⁷ See Longo CV, attached hereto as **Exhibit 4**; see also Feb. 5, 2019 Deposition of William E. Longo, Ph.D. (“Longo MDL Dep. 2/5/2019”) at 347:23-351:10, attached hereto as **Exhibit 5**.

⁸ *In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 147 (D.N.J. 2020).

⁹ **Exhibit 4**, Longo CV.

¹⁰ *Id.* at ¶ 3.

¹¹ *Id.* at ¶ 4.

¹² *Id.*

¹³ *Id.* at ¶ 7.

the proper protocol to be used when analyzing the behavior of asbestos products, including “Settled Dust: Asbestos and Other Particulates,” “The Role of the Laboratory Manager, Quality Assurance Officer and the Analyst for NIST Accreditation,” and “Fundamentals of Asbestos Analysis by TEM.”¹⁴

At MAS, Dr. Longo analyzes and studies a wide spectrum of products and associated chemicals, including the levels of asbestos fibers released under certain circumstances.¹⁵ Dr. Longo performs these tests under rigorously controlled laboratory conditions following the governmental standards promulgated by NIOSH and the EPA.¹⁶ As a member of ASTM, Dr. Longo was responsible for writing the ASTM asbestos dust analysis standards.¹⁷

In addition, Dr. Longo has published numerous articles on the subject of the analysis and testing of asbestos-containing materials, including the quantification of asbestos particles released upon manipulation of these asbestos products in the manner performed in the work environment.¹⁸ His articles include Demonstration of the Capability of Asbestos Analysis by Transmission Electron Microscopy in the 1960s in *Microscope*; Asbestos Exposure During and Following Cable Installation in the Vicinity of Fireproofing in *Environmental Choices Technical Supplement*; Fiber

¹⁴ *Id.*

¹⁵ *Id.* at ¶ 6.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.* at ¶ 8.

Release During the Removal of Asbestos-Containing Gaskets: A Work Practice Simulation, published in the *Applied Occupational and Environmental Hygiene Journal* in 2002; and Zonolite Attic Insulation Exposure Studies, in the *International Journal of Occupational Environmental Health* (2010).¹⁹ More recently, Dr. Longo's testing of J&J cosmetic talcum powder products for asbestos was discussed in a published peer reviewed article, which concluded there is "evidence of the causal link between asbestos, talc, and ovarian cancer and indicate[d] that asbestos is present in consumer talc products at a level sufficient to cause disease."²⁰

Dr. Longo has tested for the presence of asbestos in materials for over 35 years.²¹ Dr. Longo was selected to serve on the EPA peer review group for their asbestos screening program, and to provide guidance to the EPA on the proper methodologies for testing samples for asbestos.²² He was further selected to serve on a second EPA committee to determine the asbestos concentrations per area of building dust.²³ This collaboration with the EPA resulted in the publication of the American Society for Testing of Materials ("ASTM") publication D-5755 for analysis of asbestos in building materials. He chaired the EPA committee that developed the

¹⁹ *Id.*

²⁰ Joan E. Steffen, et al., *Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders—A Case Series*, J. Occup. and Environ. Med., Feb. 2020, 62(2) at e73, attached hereto as **Exhibit 6**.

²¹ Longo Hr'g Tr. 7/24/2019, 7/24/2019, at 445:13-15, attached hereto as **Exhibit 7**.

²² *Id.* at 448:9-449:4.

²³ *Id.* at 449:16-450:24.

standardized test method for testing materials for asbestos with a transmission electron microscope (“TEM”), resulting in the publication of ASTM D 5755-55. The ASTM 5755 standard was a byproduct of consensus among multiple scientists, including scientists consulting for J&J, on the best method to test materials for the presence of asbestos by use of transmission electron microscopy.²⁴ Ultimately, Dr. Longo testified on December 10, 2019 before the U.S. House of Representatives in a hearing before the Subcommittee on Economic and Consumer Policy of the Committee on Oversight and Reform regarding the examination of carcinogens in talc and the best methods for asbestos detection.²⁵

Because of his specialized knowledge and expertise, Dr. Longo is asked to consult in litigation with plaintiffs’ firms and defense firms, and outside of litigation with well-known companies such as Hitachi, Intel, BMW, Honda, Dow, and others.²⁶ Dr. Longo is also routinely asked to perform work for clients not involved in litigation and utilizes the same generally accepted methodologies and analysis for testing outside of litigation as he does in the courtroom.²⁷ Dr. Longo has, unsurprisingly, been the subject of *Daubert* challenges—as have most experts in litigation. Dr. Longo’s testimony has been overwhelmingly admitted in the face of such challenges, contrary

²⁴ *Id.* at 450:25-451:3; 451:4-453:22; 453:8-454:21

²⁵ Dec. 10, 2019 Hr’g Tr. “Examining Carcinogens in Talc and the Best Methods for Asbestos Detection”, Subcommittee on Economic and Consumer Policy (Committee on Oversight and Reform), attached hereto as **Exhibit 8**.

²⁶ **Exhibit 4**, Longo CV, at ¶ 9.

²⁷ *Id.* at ¶ 10.

to J&J's representations, *in this decade and those prior*.²⁸ More importantly and directly relevant to this case, Dr. Longo's testimony with respect to MAS's testing of J&J talcum powder and corresponding findings has been admitted in the vast majority of courts in which he has been proffered as an expert.²⁹

As set forth below, Dr. Longo's prior testimony regarding MAS's testing of J&J Talcum Powder Products in trials across the country clearly demonstrates his qualifications and the foundation for the testing methodology.

- The *Herford* case in California.³⁰ The court determined that Dr. Longo's testimony was admissible circumstantial evidence of the plaintiff's asbestos exposures from the product; Dr. Longo's methodology was scientifically supported; and the disagreements among the expert witnesses should be decided by the jury.³¹
- The *Lanzo* case in New Jersey. After a preliminary hearing, Judge Viscomi determined that Dr. Longo's testimony was admissible, and that the defendants' cross-examination point affected only the weight of the evidence.

What the Court found compelling was the testimony of Dr. Longo insofar as he found that by doing the testing, the consistency of the product throughout and some of the tests that he conducted revealed the presence of asbestos. Some did not and so based upon his argument as to the consistency, which the Court found compelling, as to it being an indicia of reliability, the Court finds that it would be appropriate to deny the motion to exclude, allow the testimony, but certainly there are issues that would go to the weight of the evidence.³²

²⁸ See **Exhibit 9**, Longo and MAS admissions spreadsheet, attached hereto; *see also* **Exhibit 5**, Longo MDL Dep. 2/5/2019 at 351:11-21.

²⁹ *Id.*

³⁰ See **Exhibit 10**, *Herford* Hr'g Tr., Sept. 27, 2017, attached hereto.

³¹ *Id.*

³² See **Exhibit 11**, *Lanzo* Hr'g Tr., Dec. 22, 2017, attached hereto.

- The *Anderson* case in California. Dr. Longo was admitted “to testify as to the methods he used in regard to analyzing samples and his analyzation [sic] as to other items as well. I think that’s a determination for the jurors to make in regard to whether or not they accept his opinion or not and what weight they give his opinion. So, the court would allow Dr. Longo’s methodology or his methods that he relied upon in regard to testing and any other test results that he may testify to....”³³
- The *Boyd-Bostic* case in South Carolina.³⁴ The court determined that Dr. Longo has specialized knowledge that would assist the trier of fact, and is qualified by his knowledge, skill, experience, training, and education.³⁵ The court further determined that Dr. Longo’s testimony as to the presence or absence of asbestos in talcum powder products was admissible, especially talcum powder samples directly from J&J “because J&J would have had it for all that time period.”³⁶
- The *Ingham* case in St. Louis.³⁷ The court permitted Dr. Longo to testify, explaining his analysis, findings of bundles, findings of fibers, and number of fibers in bundles per gram of talcum powder.³⁸
- The *Henry* case in New Jersey. The court permitted Dr. Longo’s testimony for the same reasons as in the *Lanzo* case.³⁹
- The *Allen* case in California. The court again permitted Dr. Longo to testify regarding his generally recognized and accepted methodologies.⁴⁰

³³ See **Exhibit 12**, *Anderson* Trial Tr., May 15, 2018, attached hereto at 1694:21-1695:3.

³⁴ See **Exhibit 13**, *Boyd-Bostic* Hr’g Tr., May 11, 2018, attached hereto at 98:1-100:8, 122:5-125:10.

³⁵ *Id.* at 98:1-18.

³⁶ *Id.* at 124:20-125:10.

³⁷ See **Exhibit 14**, *Ingham* Trial Tr. Vol. 6A, June 7, 2018, at 973:13-25, 979:15-982:9, 985:12-986:16.

³⁸ *Id.*; see also *Ingham* Mot. Hr’g Tr., May 29, 2018, at 115:6-120:15, attached hereto as **Exhibit 15**.

³⁹ See **Exhibit 16**, *Henry* Mot. Hr’g Tr., Sept. 14, 2018, at 82:25-86:22.

⁴⁰ See **Exhibit 17**, *Allen* Trial Tr. Vol. XVI, Oct. 17, 2018, at 3133:16-3136:10.

- The *Leavitt* case in California. The court admitted Dr. Longo as an expert on the topics of material science, testing for asbestos, bulk air and tissue, and assessment of exposure from an industrial hygiene approach.”⁴¹
- The *Olson* case in New York. The court permitted Dr. Longo to testify as J&J’s arguments were “a matter for the jury. It goes to the weight of the evidence, and it’s not something [for which] the [c]ourt can exclude a witness.”⁴²
- The *Rimondi* case in New Jersey. The court determined that Dr. Longo “qualified as an expert in the fields of material scientist - - material science, testing of asbestos and assessment of asbestos exposures.”⁴³
- The *Schmitz* case in California.⁴⁴ Dr. Longo was admitted to testify, with the court certifying Dr. Longo “as an expert in material science, forensic engineering, testing for asbestos, and exposure to asbestos.”⁴⁵
- The *Sizemore* case in South Carolina.⁴⁶ The court permitted Dr. Longo to testify regarding his testing, methodology, and findings, including the range of asbestos exposure experienced by talcum powder users.⁴⁷ The court concluded “[a]nd all the other things you wish I would do about Dr. Longo - - ...[t]hat big, huge hunk of paper that would exclude him or limit his opinions, I’m not going to do that.”⁴⁸
- The *Valadez* case in California. The Court permitted Dr. Longo to testify to his testing, methodology, including the amount of exposure to asbestos experienced by a talcum powder user.
- The *Perry* case in South Carolina.⁴⁹ The Court specifically denied the defendants’ motion to exclude the testimony by Dr. Longo concerning his

⁴¹ See **Exhibit 18**, *Leavitt* Trial Tr. Feb. 7, 2019, at 27:8-21, 52:18-22.

⁴² See **Exhibit 19**, *Olson* Trial Tr., Feb. 25, 2019, at 1456:2-1471:23.

⁴³ See **Exhibit 20**, *Rimondi* Trial Tr. Vol. 1, Mar. 5, 2019, at 6:18-38:9.

⁴⁴ See **Exhibit 21**, *Schmitz* Trial Tr. Apr. 30, 2019, at 44:13-50:1.

⁴⁵ *Id.* at 62:13-77:10.

⁴⁶ See **Exhibit 22**, *Sizemore* Pretrial Mot. Hr’g Tr., May 7, 2019, at 95:4-5, 96:16-97:3, 99:23-101:5, 102:14-25, 103:6-12.

⁴⁷ *Id.* at 105:14-20, 107:20-108:6.

⁴⁸ *Id.* at 108:7-12.

⁴⁹ See **Exhibit 24**, *Perry* Pretrial Mot. Hr’g Tr., July 30, 2024, at 218:21-220:6.

alleged identification of chrysotile asbestos in J&J products via polarized light microscopy (“PLM”) dispersion staining.⁵⁰ In so ruling, the Court stated: “Longo has his opinions. He’s cross-examined at length about them. I have ruled in every case he’s been on that he can testify.”⁵¹

Numerous juries throughout the country have thus been allowed to consider Dr. Longo’s expert testimony, including three in New Jersey state court. The *Leavitt*, *Olson*, *Rimondi*, and *Sizemore* juries have considered MAS’s testing and results conducted pursuant to this Court’s comprehensive, stipulated order in these proceedings. Conversely, the only court that has excluded the specific evidence at issue in this motion did so without allowing oral argument or conducting a Rule 104 hearing. The Court’s decision was not based on Dr. Longo’s methodologies, but over a concern about the chain of custody of the samples tested, which is not present here.⁵² To be clear, the samples that MAS tested in the MDL were produced by J&J directly to the PSC in compliance with this Court’s order.⁵³

⁵⁰ *Id.* at 219:2-8 (“This is about specific opinions that Dr. Longo has concerning his PLM heavy liquid separation testing for chrysotile, not for amphibole, not as TEM. It is specific to his chrysotile findings and the methodology that he is using, but not only that, but the way he is applying the methodology.”).

⁵¹ *Id.* at 219:20-24.

⁵² See Order dated Jul. 23, 2018 in *Weirwick v. Brenntag North America, et al.*, No. BC656425 (Cal. Super. Ct.), at Exhibit B, p. 27-35, attached hereto as **Exhibit 25**.

⁵³ See Agreed Order and Stipulation Regarding the Johnson & Johnson Defendants’ Production of Talcum Powder Products & Talc Samples (ECF Dkt. 4032); Agreed Order and Stipulation Regarding Production of Talc Samples from Imerys Talc America, Inc. (ECF Dkt. 4757).

Since Dr. Longo issued his February 1, 2019 Second Supplemental Report,⁵⁴ which Judge Wolfson considered in the April 27, 2020 *Daubert* Opinion,⁵⁵ Dr. Longo tested 43 additional samples, which are discussed in his Third and Fourth Supplemental Reports.⁵⁶ As Dr. Longo explains, when the last MDL report was issued, MAS was not using the heavy liquid separation (“HLS”) sample preparation method to test talcum powder products for chrysotile asbestos.^{57, 58} That sample preparation methodology, which was first developed by the Colorado School of Mines, uses high density liquids and centrifugation to separate minerals thereby increasing detection limits. Of the samples discussed in the Fourth Supplemental Report, Dr. Longo found chrysotile or amphibole asbestos in 93% of them.

B. Dr. Mark Rigler

Dr. Rigler has a Bachelor of Science degree in biology from Villanova University, and also holds a Ph.D. in microbiology from the University of Georgia with an emphasis on using electron microscopy techniques.⁵⁹ He has been trained in

⁵⁴ See Amended Expert Report of William E. Longo, PhD and Mark W. Rigler, PhD, The Analysis of Johnson & Johnson’s Historical Product Containers and Imerys’ Historical Railroad Car Samples from the 1960s to the Early 2000s for Amphibole Asbestos (February 2, 2019), attached hereto as **Exhibit 26**.

⁵⁵ *Id.* at 147.

⁵⁶ The Fourth Supplemental MDL Report 4/29/24 (**Exhibit 27**) corrects certain typographical errors in the Third Supplemental MDL Report 11/17/23 (**Exhibit 28**).

⁵⁷ As discussed in the 2019 Second Supplemental Report, Dr. Longo had previously used a sample preparation methodology to concentrate amphibole asbestos.

⁵⁸ **Exhibit 27**, Longo Fourth Supplemental MDL Report, pgs. 2-8.

⁵⁹ See Rigler CV, attached hereto as **Exhibit 29**; Feb. 6, 2019 Deposition of Dr. Mark Rigler (“Rigler MDL Dep.”) at 219:21-220:8, attached hereto as **Exhibit 30**.

all phases of electron microscopy including morphological identification of tissues and materials, selected area electron diffraction (SAED), and energy dispersive x-ray analysis (EDS).⁶⁰ Dr. Rigler also understands the methods of tissue processing that are used by clinical pathologists, which include histological sample preparation for histological slide preparation and tissue analysis and identification at the optical microscopy level.⁶¹ Dr. Rigler's training and experience has included all phases of tissue preparation and tissue sectioning for transmission electron microscopy, including tissue preparation for scanning electron microscopy and tissue preparation for cryo-electron microscopy.⁶²

Dr. Rigler previously worked as a licensed clinical electron microscopy Laboratory Director for the State of Georgia.⁶³ He was employed at MAS, LLC as the Chief Science Officer and Senior Consultant, where for approximately 30 years he directed the analysis of a variety of materials and biological tissues by transmission and scanning electron microscopy.⁶⁴ This work has included the analysis of mineralogical particulates and microfibers including tremolite, actinolite, anthophyllite, chrysotile, amosite, and crocidolite asbestos.⁶⁵

⁶⁰ **Exhibit 29**, Rigler CV at ¶ 2.

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.* at ¶ 2.

⁶⁴ *Id.* at ¶¶ 2-3; **Exhibit 30**, Rigler MDL Dep. at 220:20-223:2.

⁶⁵ **Exhibit 29**, Rigler CV at ¶ 2.

Dr. Rigler has designed custom analytical protocols for product and chemical studies and has extensive laboratory management experience.⁶⁶ Dr. Rigler helped develop the quality control program at MAS which requires certification by the National Institute of Standards and Technology, National Voluntary Laboratory Accreditation Program (“NIST NVLAP”).⁶⁷ Dr. Rigler was responsible for ensuring that the studies conducted at MAS follow the quality protocols and standards required by various lab certification bodies.⁶⁸

Because of his experience in this area, Dr. Rigler, now Principal Consulting Scientist at Aspex, LLC, has also testified in other litigation.⁶⁹ His testimony has never been excluded on *Daubert* grounds.⁷⁰ Finally, Chief Judge Wolfson applied her ruling permitting Dr. Longo’s TEM testimony in total to Dr. Rigler in an order entered June 24, 2020.⁷¹

C. Dr. Longo’s laboratory, MAS, LLC, and his analysts are certified to test materials for the presence of asbestos.

Dr. Longo’s laboratory, MAS, LLC, is certified by the National Voluntary Laboratory Accreditation Program, run by the National Institute of Standard and Technology, for the analysis of asbestos in materials.⁷² MAS is a leading engineering

⁶⁶ **Exhibit 30**, Rigler MDL Dep. at 224:3-225-4.

⁶⁷ *Id.* at 224:3-225-4.

⁶⁸ *Id.* at 225:10-227:13.

⁶⁹ *See* Rigler Affidavit at ¶ 3, attached hereto as **Exhibit 31**.

⁷⁰ *Id.*

⁷¹ *See* ECF Dkt. 13715 at 2.

⁷² **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, 7/24/2019, at 454:22-455:23.

consulting firm, which provides a broad range of services including environmental and industrial hygiene and emissions testing.⁷³ To perform its work, MAS has employees with expert knowledge of a broad range of fields including materials sciences, chemistry, physics, biology, industrial hygiene, geology, mechanical engineering, and microscopy. The American Industrial Hygiene Association has accredited MAS for measurement of asbestos fibers by phase contrast microscopy and for the analysis of bulk samples of asbestos.⁷⁴ In addition, the National Volunteer Laboratory Accreditation Program has certified MAS for measurement of bulk samples and air samples of asbestos. MAS also performs consulting work for government agencies such as the Centers for Disease Control and the National Institutes of Health.⁷⁵ Further, MAS worked as an expert for the City of New York and the State of New York in their respective litigation against asbestos companies.⁷⁶ MAS has been involved in testing asbestos-containing materials for over thirty years and has analyzed hundreds of thousands of asbestos samples.⁷⁷ MAS has been retained by both plaintiffs and defendants in asbestos litigation.⁷⁸ MAS studies and videotape demonstrations are used for educational and training purposes in conjunction with the American Industrial Hygiene Association, American Society of

⁷³ See Longo Certification at ¶ 9, attached hereto as **Exhibit 32**.

⁷⁴ *Id.* at ¶ 3.

⁷⁵ *Id.* at ¶ 9.

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.* at ¶ 11.

Safety Engineers, the Environmental Institute, AHERA certification training and the U.S. Public Health Service.⁷⁹

MAS utilizes multiple, standardized analytical techniques. The MAS methods include the very testing techniques routinely employed by and available to industry in the 1960s and 70s, as well as updated, standardized testing procedures.⁸⁰ For example, the aspect-ratio distribution for the asbestos fibers identified by Dr. Longo in his testing are virtually identical to a number of other analyses on undisputed asbestos samples, including those conducted by former consultant to J&J, Dr. Alice Blount, the National Institute of Standards Technology (NIST), and the United States Geological Survey (USGS).

All of Dr. Longo's laboratory analysts at MAS were required to follow the generally accepted test methods for TEM and PLM.⁸¹ They receive extensive training in the use of TEM and PLM and have decades of experience. All of his analysts have a bachelor's degree in biological science.⁸² Anthony Keaton, who performed the TEM analysis on J&J talc, is a geologist and mineralogist. Dr. Longo's manager of PLM and TEM has fifteen years of experience.⁸³ As for the PLM testing,

⁷⁹ *Id.*

⁸⁰ *Id.* ¶ 12.

⁸¹ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, 7/24/2019, at 649:20-25.

⁸² *Id.* at 500:20-501:16; 501:17-502:1.

⁸³ *Id.* at 500:20-502:1; 501:17-502:1; 502:6-16.

Paul Hess performed the testing on J&J's talc. He is a microscopist with 34 years of experience who has performed on average, over 10,000 PLM tests a year.⁸⁴

Dr. Longo assures that the correct protocols are being used, double-checks work, and reviews the images underlying the results.⁸⁵ He confirms the reliability of his analysts by their supervision, the quality control, the co-efficient variation for error rates, and continual monitoring.⁸⁶

Drs. Longo and Rigler are uniquely qualified to analyze the asbestos content of the J&J Talcum Powder Products. Because Drs. Longo and Rigler have special knowledge, skill, experience, training, and education on the topics to which they may testify, their testimony is admissible under the Federal Rules of Evidence.

LEGAL STANDARDS

The PSC incorporates herein the *Plaintiffs' Steering Committee's Memorandum of Law Regarding the Rule 702 Standard* ("Rule 702 Standard Brief").

ARGUMENT

The methodologies of Dr. Longo and Dr. Rigler are time-tested, reliable, and well-accepted. Under Rule 702, their testimony should therefore be allowed.

According to the Third Circuit, the Federal Rules of Evidence embrace a liberal policy of admissibility.⁸⁷ An "expert's testimony is admissible so long as the

⁸⁴ **Exhibit 33**, Deposition of Paul Hess ("Hess Dep.") July 10, 2024, at 10:23-11:6.

⁸⁵ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, 7/24/2019, at 502:6-17.

⁸⁶ *Id.* at 650:1-10.

⁸⁷ *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008).

process or technique the expert used in formulating the opinion is reliable.”⁸⁸ This is not a demanding test. It does not require plaintiffs to “prove their case twice.”⁸⁹ This is because the “evidentiary requirement of reliability is lower than the merits standard of correctness.”⁹⁰ To satisfy that standard, the “expert’s opinion must be based on the ‘methods and procedures of science’ rather than on ‘subjective belief or unsupported speculation; the expert must have ‘good grounds’ for his or her belief.”⁹¹ While J&J disagrees with the conclusions reached by Drs. Longo and Rigler, none of its criticisms of their opinions cast doubt on the fact that they have “good grounds” for each and every one of their opinions considering that J&J has repeatedly found over the last fifty years that JBP contained “sub-trace quantities of tremolite or actinolite . . . , and these might be classified as asbestos fiber.”⁹²

I. Chief Judge Wolfson’s ruling, permitting Dr. Longo to testify regarding his TEM testing, should not be disturbed.

In this Court’s April 30, 2024 Memorandum Order (ECF No. 32122),⁹³ the Court gave the parties guidelines for refiling *Daubert* motions and specifically required a refiled motion to “identify either (1) that Chief Judge Wolfson’s previous

⁸⁸ *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994).

⁸⁹ *Id.* at 744.

⁹⁰ *Id.*

⁹¹ *Id.* at 742 (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993)).

⁹² J&J Memo from D. R. Petterson to D. D. Johnson (Apr. 26, 1973), attached hereto as **Exhibit 2**.

⁹³ On June 24, 2020, the Court entered a letter Order finding that the Court’s *Daubert* decision regarding Dr. Longo’s testimony applied equally to Dr. Rigler. *See* Order of June 24, 2020 (ECF Dkt. 13715).

Opinion *demonstrably fails* to adhere to Rule 702 as clarified by the 2023 amendments; or (2) new science is shown to directly contradict or challenge Chief Judge Wolfson’s previous findings.”⁹⁴ First, J&J did not and cannot demonstrate that Chief Judge Wolfson’s Opinion admitting Dr. Longo’s TEM testimony⁹⁵ *demonstrably failed* to adhere to Rule 702 as clarified by the 2023 amendments. Second, J&J did not identify any “new science” that contradicts or challenges Dr. Longo’s TEM methodology. Therefore, J&J’s motion to exclude Dr. Longo’s TEM opinions should be denied.

It is clear from the 2023 Advisory Committee Notes that the amendments to Rule 702 are meant to “clarify and emphasis that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule.”⁹⁶ The amendment did not change the rule’s substantive requirements.⁹⁷ Under

⁹⁴ April 30, 2024 Order at 6 (ECF Dkt. 32122).

⁹⁵ *In re: Johnson & Johnson Talcum Powder Prods., Mktg., Sales Practices & Prods. Litg.*, 509 F. Supp. 3d 116, 147-154 (D.N.J. 2020) (“Chief Judge Wolfson’s Opinion”).

⁹⁶ Adv. Com. Notes to Rule 702 (2023).

⁹⁷ See *Johnson v. Comodo Grp., Inc.*, No. 2:16-04469, 2024 WL 2933195, at *4 n.6 (D.N.J. June 10, 2024) (unpublished) (“The amendment does not substantively alter Rule 702 but rather ‘clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000—requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard.’”) (quoting Adv. Com. Notes to Rule 702 (2023)); *Walden v. Bank of N.Y. Mellon Corp.*, No. 2:20-CV-01972, 2024 WL 343087, at *2 n.3 (W.D. Pa. Jan. 30, 2024) (*Daubert* legal standard not substantively changed by 2023 amendment); *Costello v. Mountain Laurel Assur. Co.*, No. 2:22-CV-35, 2024 WL 239849, at *4 (E.D. Tenn. Jan. 22, 2024) (“these amendments were intended to clarify the requirements of the Rule, not to make substantive changes.”).

Daubert and Rule 702, this Court must examine the reliability of an expert's methodology, not the correctness of the expert's conclusions. In determining reliability, the Court should examine "the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion."⁹⁸ The proponents of the testimony are required to show *reliability* by a preponderance of the evidence.⁹⁹ However, whether the expert's testimony is credible, carries weight or is correct is for the factfinder to determine, not the court.¹⁰⁰

Here, Chief Judge Wolfson thoroughly examined every step of Dr. Longo's TEM analysis and found it to be "reliable for the purposes of admission under *Daubert*."¹⁰¹ In finding Dr. Longo's TEM analysis reliable, Chief Judge Wolfson specifically recognized that "[t]he proponent bears the burden of establishing admissibility by a preponderance of the evidence."¹⁰² The preponderance of the evidence standard of Rule 104(a) is the clarification made to Rule 702 by the 2023 amendments.¹⁰³ Because Chief Judge Wolfson applied this standard, J&J cannot demonstrate that her opinion *demonstrably* failed to adhere to Rule 702. This Court should accordingly deny J&J's motion to exclude Dr. Longo's TEM opinions. In

⁹⁸ *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012).

⁹⁹ *Oddi v. Ford Motor Co.*, 234 F.3d 136, 145 (3d Cir. 2000).

¹⁰⁰ *In re: Valsartan, Losartan, and Irbsartan Prods. Liab. Litig.*, No. 19-2875, 2024 WL 65132, at *3 (D.N.J. Jan. 5, 2024) (citing *Kannankeril v. Terminix Intern., Inc.*, 128 F.3d 802, 810 (3d Ci. 1994)).

¹⁰¹ Chief Judge Wolfson's Opinion, 509 F. Supp. 3d at 148.

¹⁰² *Id.* (citing *Crowley v. Chait*, 322 F. Supp. 2d 530, 537 (D.N.J. 2004)).

¹⁰³ Adv. Com. Notes to Rule 702 (2023).

any event, should the Court decide to consider J&J's motion to exclude Dr. Longo's TEM opinions on the merits, it should be denied for the following reasons.

A. Drs. Longo and Rigler did not "re-define" asbestos.

Drs. Longo and Rigler did not "re-define" asbestos or asbestiform materials to reach a desired result. Unlike J&J, they employed standard and scientifically accepted definitions and methodologies in conducting their analyses.

1. What is asbestos?

Asbestos is defined, for health and regulatory purposes, by various agencies such as the Occupational Safety and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA), and the United States Environmental Protection Agency (EPA). Two areas of critical inquiry in this case are whether the talcum powder that Plaintiffs used (and were exposed to) contained asbestos, and whether such exposure provides a biologically plausible explanation for the cause of their ovarian cancer. This issue is one of health and safety, not an examination as to the commercial viability of asbestos.

There are several definitions of asbestos that differ based on the use and context. The United States Geological Survey has explained this issue well:

Asbestos has been defined by workers in many disciplines including those in the commercial asbestos industry and the mining industry, the public health community, those in the regulatory community, and the mineralogical and geological sciences. Many of these definitions are given in a compilation prepared by Lowers and Meeker (2002). It is clear from that compilation that ***the definition of asbestos (and related***

terminology) can vary depending on the source and purpose. For example, a definition of asbestos appropriate for the asbestos cloth industry, which might require a very long, thin, highly flexible fiber might be different from that used in the asbestos cement pipe industry which could utilize a more brittle and perhaps shorter and wider fiber. Both of *these definitions could be vastly different from those used in the health community, where the concern is exposure, risk, and ultimately disease.*¹⁰⁴

The definition applied by J&J's experts¹⁰⁵ is a commercial one used "for analysis of commercial-grade asbestos found in the workplace and in consumer products . . . developed to specifically analyze for commercial-grade asbestos in media where there may be reason to expect its presence."¹⁰⁶ Asbestos—as found in commercial asbestos products or an asbestos vein being analyzed for commercial viability—is entirely different from asbestos naturally occurring as an accessory mineral to talc. "In order to be of commercial value, asbestos must be in sufficient quality and purity for the application, and it must occur in sufficient abundance to be mined at a profit."¹⁰⁷ This definition, while central in some contexts, is simply beside the point in the context of this litigation, which involves significant risks of cancer faced by American women. As the USGS has noted:

[The] criteria sometimes employed for identification and characterization of commercial-grade asbestos ... have not been shown to directly contribute to health effects and should not be the

¹⁰⁴ See USGS, Tabulation of Asbestos-Related Terminology (2002) at 37, attached hereto as **Exhibit 34** (emphasis added).

¹⁰⁵ This definition was offered by J&J's expert Dr. Sanchez, one of J&J's experts here, as well as Drs. Dyar and Wylie.

¹⁰⁶ **Exhibit 34**, USGS at 37.

¹⁰⁷ *Id.*

sole basis for exclusion of materials that may otherwise meet demonstrated health-related criteria such as length, width, bulk chemistry, and perhaps surface chemistry.... [T]he counting criteria developed for analysis of asbestos in the workplace or in commercial products may not be appropriate for direct application to what is currently referred to as naturally occurring asbestos.¹⁰⁸

No one would suggest that the asbestos found as an accessory mineral in talc is a commercially viable source for asbestos mining; it is rather regarded as “naturally occurring.” Commercial viability may rest on factors wholly unrelated to health and welfare, including the location, amount, and extractability of the deposit. This case does not seek an answer to the question: *Are there commercially viable asbestos deposits within J&J’s source talc?* Instead, the relevant inquiry is *whether J&J’s talcum powder products contained asbestos fibers that can cause disease.* The only appropriate counting criteria and analysis methods are, therefore, those applied by the regulatory agencies that regulate asbestos-related health hazards. And importantly, none of those regulatory agencies have developed standards that mandate that an analyst somehow meet the general definition of asbestos by analytically determining tensile strength and/or flexibility.^{109, 110}

¹⁰⁸ *Id.* at 42 (emphasis added).

¹⁰⁹ Pursuant to such standards amphibole fibers or bundles are “defined to have an aspect ratio equal or greater than 5-to-1 and a minimum length of 5.0” with substantially parallel sides. **Exhibit 5**, Longo MDL Dep. 2/5/2019, at 229:230:1; *see also* Longo Second Supplemental MDL Report at 12, attached hereto as **Exhibit 26**.

¹¹⁰ *Id.*

Once a fiber is identified in accordance with the standard's counting criteria,¹¹¹ the method employed by Drs. Longo and Rigler mandates additional steps to permit identification of the fiber as regulated asbestos or otherwise.¹¹² The IWGACP's recommended testing criteria supports the counting method utilized by Drs. Longo and Rigler.¹¹³ As Dr. Longo explained, "[t]he whole protocol determines what is a regulated asbestos, and then the asbestiform and high tensile strength is just a general definition."¹¹⁴

2. Public health regulators and scientists do not distinguish between asbestos fibers and cleavage fragments.

The Court may wonder why there is a definitional divide between the parties. To be clear, it is J&J that is attempting to apply its own definition of "asbestos" in an effort to deflect scrutiny of the health hazards of its product—a tactic that is consistent with the strategy J&J has employed to evade and deflect throughout the last fifty years. By simply redefining the term "asbestos," J&J is arguing that fibers meeting the regulatory definition for asbestos are in fact non-asbestos "cleavage

¹¹¹ Standard counting criteria relied upon by MAS and Drs. Longo and Rigler includes AHERA and ASTM. Admittedly, AHERA is used "to clear schools after abatement." **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, 7/24/2019, at 493:12-494:5. The ASTM method—with the same standard counting rules as AHERA—relied upon by MAS and Drs. Longo and Rigler, however, has nothing to do with clearing schools, and is used to determine if there is contamination." *Id.* at 449:16-452:1.

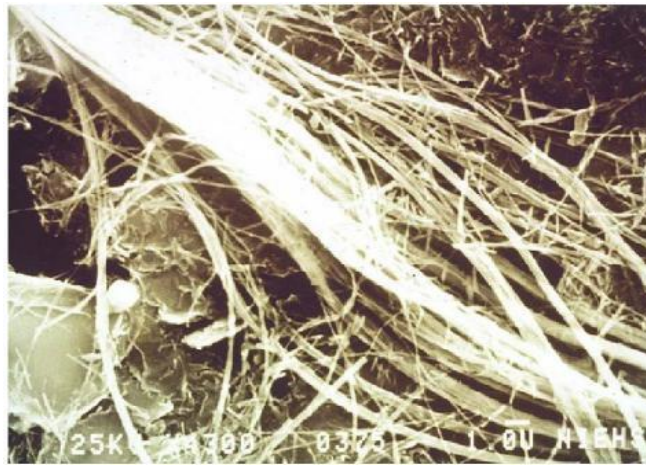
¹¹² **Exhibit 5**, Longo MDL Dep. at 230:14-17; *see also* **Exhibit 26**, Longo Second Supplemental MDL Report at 12.

¹¹³ *See* **Exhibit 1**, White Paper at 19-20.

¹¹⁴ **Exhibit 5**, Longo MDL Dep. at 230:8-17.

fragments.” This is important, of course, as fibers meeting the regulatory definition for asbestos have been found in both J&J’s talc ore and end-products.

Asbestos fibers are not uniform. They come in an infinite variety of shapes and sizes. Below is a picture of chrysotile asbestos. In this picture alone, there are thousands of fibers of all different morphologies (shapes): long, short, fat, thin, straight, curved, bundled, alone, etc.



The agencies that regulate asbestos have rejected the false distinction between “asbestos” and “cleavage fragments” that J&J is once again trying to impose on this Court. These agencies have acknowledged asbestos fibers are not uniform but come in an infinite variety of shapes and sizes, and that the accepted science is that all types of fibers can cause disease. Responding to a report by the R.J. Lee Group—an expert J&J has previously utilized in talcum powder litigation, though not in this MDL—the EPA stated:

The R. J. Lee Report Applies a Geologic Definition rather than a Public Health Definition to Characterize Microscopic Structures - The R. J.

Lee Report relies heavily on the geologic distinction between asbestos fibers and cleavage fragments of the same dimensions, with the implication that exposure to cleavage fragments is benign and of little or no health significance. ***For the purposes of public health assessment and protection, EPA makes no distinction between fibers and cleavage fragments of comparable chemical composition, size, and shape.***¹¹⁵

The EPA concluded that “[i]n terms of epidemiological data and health outcomes, the ***cleavage fragment argument is without merit.***”¹¹⁶ As this shows, all regulated fibers are significant from a public health perspective.

Public health and governmental agencies maintain the same or similar definitions for what constitutes a countable asbestos fiber when evaluating asbestos exposure because ***the distinction Dr. Wylie draws has no demonstrated impact on the ability to cause disease.*** The argument J&J is making before this Court, as the EPA has stated, falls outside the bound of accepted science in the regulatory community. This Court should likewise reject it.

3. Regulators and J&J (outside of litigation) employ similar methodology to identify asbestos.

Putting aside J&J’s facile distinction between “asbestos” and “cleavage fragments” addressed above, there is near unanimity among regulators—and J&J—concerning the appropriate identification of asbestos fibers. After confirming through analysis of crystal structure and elemental chemistry that the particle is from

¹¹⁵ EPA Response to R.J. Lee at 2-3, attached hereto as **Exhibit 35**.

¹¹⁶ *Id.* at 11-12 (emphasis added).

the asbestos mineral family, the counting criteria determine what “counts” as an asbestos fiber. For reference, these include:

OSHA: A countable fiber under light microscopy is equal to or longer than 5μ (microns) and has an aspect ratio (length-to-width ratio) equal to or greater than 3:1.

MSHA: Same as OSHA.¹¹⁷

EPA/AHERA: A structure greater than or equal to .5μ in length with an aspect ratio (length -to-width ratio) of 5:1 or greater and having substantially parallel sides.

2021 IWGACP: All particles having a length ≥ 0.5 μm (micrometers) and a ratio of length to width (aspect ratio) of 3:1 or greater. It was the Interagency Working Group on Asbestos in Consumer Products’ scientific opinion that “categorizing such particles as non-asbestiform when there is ambiguity as to habit of growth” should be avoided.¹¹⁸

Johnson & Johnson: “Asbestos is defined to be...chrysotile, and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite asbestos and actinolite.” J&J defines an “asbestiform mineral” as “An elongated particle with parallel sides and an aspect ratio $\geq 3:1$.”¹¹⁹

As described above, the agencies that regulate asbestos for health and safety purposes, as well as J&J, maintain very simple definitions that recognize the diverse

¹¹⁷ In 2005, RJ Lee Group (a third-party lab used by both J&J and Imerys) urged MSHA to change its counting rules to exclude cleavage fragments. MSHA declined. *See Exhibit 36*, 73 Fed. Reg. 41 (Feb. 29, 2008), at 11286, attached hereto.

¹¹⁸ *Id.*

¹¹⁹ *See* June 28, 1977 J&J Memo “Audit Testing of Windsor 66 Talc for Asbestos,” attached hereto as **Exhibit 37**; March 8, 1989 “Analysis of Powdered Talc For Asbestiform Minerals by Transmission Electron Microscopy,” at 5, attached hereto as **Exhibit 38**; and March 21, 1995 “Analysis of Powdered Talc for Asbestiform Minerals by Transmission Electron Microscopy,” at 8, attached hereto as **Exhibit 39**.

morphology of asbestos fibers. As Dr. Longo explained in this case, a “[c]leavage fragment, typically for tremolite, is particulates that have an aspect ratio of somewhere between 1-to-1 to 1-to-2, but they will have the same chemistry and the same crystalline pattern.”¹²⁰ “[I]f it does have parallel sides, if it **does meet all the definitions** of the counting rules, you can call it what you like, but it’s regulated asbestos per the standard counting rules for every one of these TEM methods that I have referenced in my report.”¹²¹

4. J&J’s false distinction between asbestiform and non-asbestiform materials.

“Asbestiform” is a commercial geological distinction designed to designate certain asbestos deposits as commercially desirable or not. It has zero relevance to the health hazard of the material. Nonetheless, Dr. Longo has multiple reasons to conclude that what he found in the samples of J&J Baby Powder and Shower to Shower is, in fact, amphibole asbestos and not non-asbestiform chunks. Dr. Longo (1) found bundles of fibers, (2) found fibers longer than 20 microns, and (3) the average aspect ratio of the bundles and fibers he found ranged from 7:1 to over 20:1. These findings support the conclusion, based on generally recognized standards and peer-reviewed literature, that the J&J samples contain asbestos fibers.

¹²⁰ **Exhibit 5**, Longo MDL Dep. at 238:13-19.

¹²¹ *Id.* at 239:2-22 (emphasis added).

In the samples of J&J Baby Powder and Shower to Shower that Dr. Longo tested, he found multiple examples of bundles of fibers, which Professor Blount in her 1991 peer-reviewed paper instructed are always indicative of asbestiform amphiboles.¹²² Indeed, ISO 22262-1, the generally recognized standard for finding asbestos in bulk materials, states:

c) . . . observation of any of the following characteristics for the fiber type under consideration provides additional confirmation that the fibres are asbestiform:

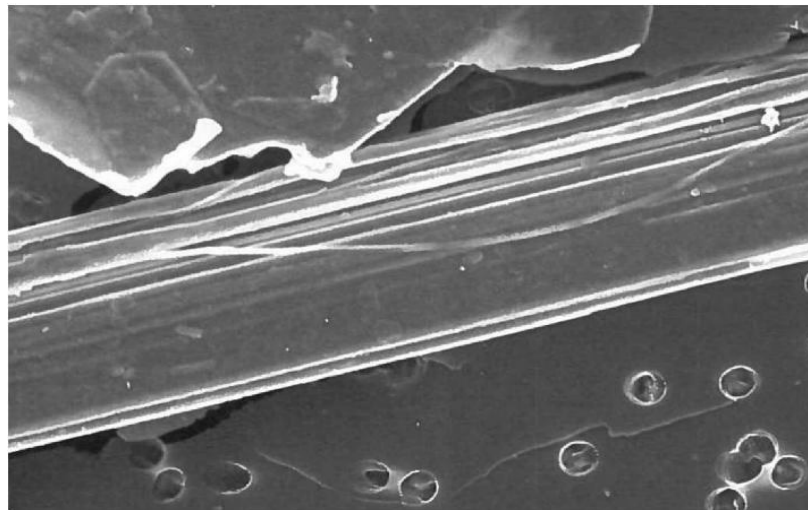
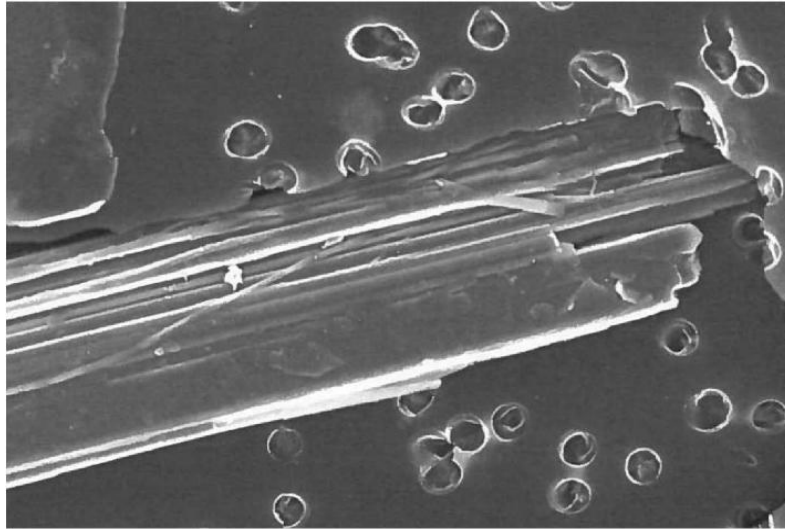
- 1) parallel fibres occurring in bundles,
- 2) fibre bundles displaying splayed ends,
- 3) fibres in the form of thin needles,
- 4) matted masses of individual fibres,
- 5) fibres showing curvature¹²³

As the Court can see from a cursory inspection of Dr. Longo's scanning electron microscope photomicrographs of a 1978 Museum Sample of Johnson's Baby Powder, there are clearly bundles of fibers meeting these characteristics:¹²⁴

¹²² See **Exhibit 40**, A. M. Blount, *Amphibole Content of Cosmetic and Pharmaceutical Talcs*, 94 Environ. Health Perspectives 225, 230 (1991) ("with true asbestiform amphiboles one generally sees some particles showing bundles of fibrils which removes any doubt about the nature of the amphibole.") (emphasis added).

¹²³ See **Exhibit 41**, ISO 22262-1, Sampling and Qualitative Determination of Asbestos in Commercial Bulk Materials (2012), at 22-23.

¹²⁴ See Longo MDL 1st Supplemental Report at 723, attached hereto as **Exhibit 42**.



(Top: Far terminal end of fiber bundle shown; Bottom: continuation of fiber bundle showing numerous thin fibrils showing flexibility).¹²⁵

The average aspect ratios (ratio of length to width) of the fibers and bundles Dr. Longo found in his testing of J&J Baby Powder and Shower to Shower were consistent with the presence of asbestiform materials, not non-asbestiform materials.

¹²⁵ See SEM Photomicrographs of 1978 JJ Museum Sample along with presentation by RJ Lee regarding asbestiform v. non-asbestiform for comparison, attached hereto as **Exhibit 43**.

Dr. Longo found that the average aspect ratio of the asbestos fibers and bundles in these samples ranged from a low of 6.8 to a high of over 20, with many individual fibers or bundles having aspect ratios well into the 30s.¹²⁶ Notably, ISO 22262-1 states that the presence of any single bundle or fiber longer than 20 microns in a sample, or a sample with fibers/bundles with an average aspect ratio higher than 5:1 supports the conclusion that the sample reviewed is asbestiform:

In general, for this part of ISO 22262, the presence of either the asbestiform or the non-asbestiform analogues of tremolite, actinolite, anthophyllite or richterite/winchite can usually be specified. If the majority of the amphibole fibres longer than 5 µm have aspect ratios equal to or lower than 5:1, and if the fibres do not exhibit any of the characteristics in c), it can be concluded that the amphibole is probably non-asbestiform, with the degree of certainty increasing with decreasing maximum aspect ratio. If any amphibole fibres longer than 5 µm with aspect ratios in the range of 20:1 or higher are observed, then it can be concluded that amphibole asbestos is probably present, with the degree of certainty increasing with increasing aspect ratio.¹²⁷

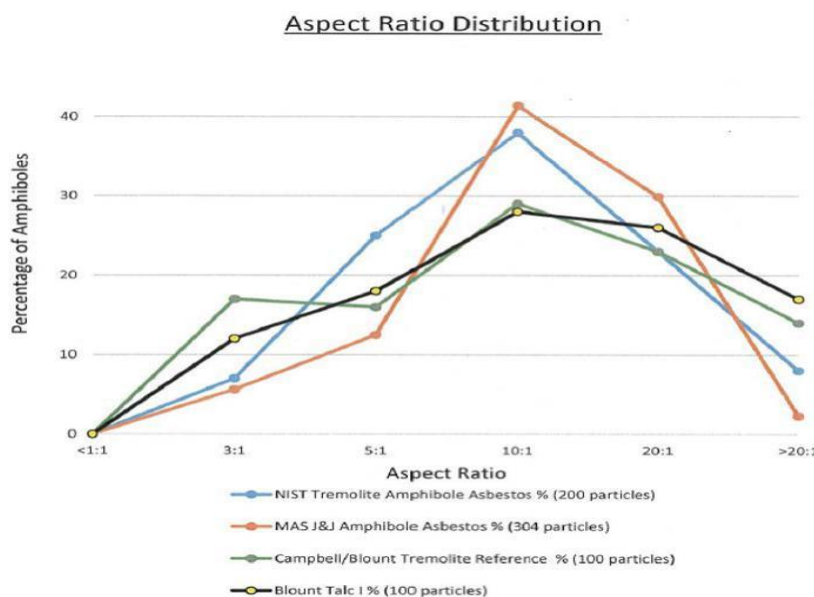
Even J&J defines asbestos “to be . . . chrysotile, and the fibrous forms of the amphibole group as represented by amosite, anthophyllite, crocidolite, tremolite asbestos and actinolite” and defines an “asbestiform mineral” as an “elongated particle with parallel sides and an aspect ratio $\geq 3:1$.”¹²⁸ The IWGACP similarly recommends that particles with an aspect ratio of $\geq 3:1$ and a length of ≥ 0.5 µm

¹²⁶ See **Exhibit 42**, Longo First Supplemental MDL Report at 34-48.

¹²⁷ **Exhibit 41**, ISO 22262-1 at 23 (emphasis added).

¹²⁸ See **Exhibit 37**, June 28, 1977 J&J Memorandum; see also **Exhibit 39**, March 21, 1995 J&J Test Method, at 7024 (emphasis added).

should be reported.¹²⁹ The aspect ratios found by Dr. Longo are consistent with both those found by Professor Blount, where the aspect ratio for “Tremolite asbestos” was 7:1, and with the 1977 Campbell Study:



B. Drs. Longo and Rigler employed scientifically accepted testing methods.

- 1. Using the heavy liquid concentration method and the TEM three-step method, Dr. Longo found asbestos in 68% of samples.**

Using TEM, Dr. Longo detected amphibole asbestos in 44 of the 72 J&J talc samples tested.¹³⁰ Dr. Longo used the heavy liquid concentration method to “concentrate the potential amphibole asbestos that might be present so that you can remove the interference of all the talc that causes a problem with the analysis,” and

¹²⁹ See **Exhibit 1**, White Paper, at 12.

¹³⁰ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 529:12-25; **Exhibit 26**, Longo Second Supplemental MDL Report at 17.

J&J did not object to the reliability of this methodology, nor to Dr. Longo's application of it.¹³¹ This method was published in Environmental Health Prospectus, part of the National Institute of Environmental Health Sciences, by J&J consultant and Rutgers' Professor of Geology Dr. Alice Blount.¹³² The heavy liquid separation method has been used for "years and years and years in the mineral industry to remove different density materials."¹³³ In 1974, the heavy liquid preparation method was developed by consultants for J&J, including Dartmouth College and Colorado School of Mines,¹³⁴ to increase the sensitivity of testing for asbestos in talc.¹³⁵ In 2014, ISO published the test method of heavy liquid separation for analyzing talc for asbestos, ISO standard 22262-2.¹³⁶ Critically, it specifies that an "Optimum Analytical Procedure" for analyzing asbestos in talc is to use the heavy liquid concentration method.¹³⁷

When J&J questioned Dr. Longo as being the "only" expert to test talc for asbestos in the manner in which he did,¹³⁸ Dr. Longo explained this difference arises solely from the fact that he applied a heavy liquid separation technique in addition

¹³¹ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 475:17-476:3.

¹³² **Exhibit 40**, A. M. Blount, *Amphibole Content of Cosmetic and Pharmaceutical Talcs*, 94 Environ. Health Perspectives 225 (1991); **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 476:4-477:10.

¹³³ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 478:22-479:5.

¹³⁴ **Exhibit 66**, Colorado School of Mines, "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers" (Dec. 27, 1973) (hereinafter "CSM").

¹³⁵ Memo from R. C. Reynolds, Jr. to Windsor Minerals Inc. (Mar. 1974), attached hereto as **Exhibit 44**; **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 479:6-480:23, 482:17-21.

¹³⁶ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 483:6-485:14, ISO 22262-2, attached hereto as **Exhibit 45**.

¹³⁷ **Exhibit 45**, ISO 22262-2 at 1, 38; **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 484:25-485:14.

¹³⁸ **Exhibit 3**, Longo Hr'g Tr. 7/24/2019, at 544:23-545:14.

to the three-step TEM published method.¹³⁹ Notably, J&J at no point argues that the heavy liquid separation method is unreliable or that Dr. Longo applied it incorrectly.

2. Dr. Longo applied the published, peer-reviewed three-step TEM method to determine if there is asbestos in J&J's talc.

Per ISO 22262-2, after employing the heavy liquid separation method by means of centrifugation, the next step is to “[i]dentify any *asbestiform* amphibole in the centrifuge according to procedures specified in ISO 22262-1” which are PLM, SEM, *or* TEM.¹⁴⁰ Dr. Longo first applied the TEM three-step method.

3. The TEM three-step method is recommended by three separate testing standards, and J&J.

The EPA AHERA, ASTM 5755, ISO 22262-1 and -2, and J&J *all* provide for the use of the TEM three-step method to analyze for asbestos in materials, including specifically for talc.¹⁴¹

- **EPA AHERA:** The EPA Asbestos Hazard Emergency Response Act (“AHERA”) method was developed by the EPA through a consensus of leading scientists to develop a test method to ensure the efficacy of abating asbestos from schools.¹⁴² The EPA AHERA was the “unanimous conclusion” of the microscopists with “extensive experience” for the detection of asbestos.¹⁴³ The EPA AHERA method eliminates all non-asbestos particles by means of the TEM three-step method:

¹³⁹ *Id.* at 544:23-545:19.

¹⁴⁰ **Exhibit 45**, ISO 22262-2, at 8, 29-30 (emphasis added).

¹⁴¹ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, 7/24/2019, at 568:16-18, 648:21-649:11, 666:9-14 (testifying that if the three-step method is met; the particle is asbestos).

¹⁴² *Id.* at 493:12-494:10.

¹⁴³ 52 Fed. Reg. 41826, 41839 (Oct. 30, 1987), attached as **Exhibit 46**; **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, 7/24/2019, at 494:6-495:4.

“Nonasbestos” is defined as “Incomplete or unobtainable ED patterns [Step #3], a nonasbestos EDXA [Step #2], or a nonasbestos morphology [Step #1].”¹⁴⁴

- **ISO 22262-1 and 22262-2:** The International Organization for Standardization (“ISO”) is a worldwide federation of national standards bodies.¹⁴⁵ ISO Method 22262-1 and -2 specify the procedures for the quantitative analysis of asbestos in talc.¹⁴⁶ ISO 22261-1 and -2 expressly provide for the use of the TEM three-step method for testing for the presence of asbestos in talc.¹⁴⁷ Additionally, ISO 22262-2 provides that for testing for the presence of asbestos in talc, the “optimum method” is to first concentrate the amphiboles by means of heavy liquid separation, and then apply the TEM or PLM.¹⁴⁸
- **ASTM 5755:** American Society for Testing Materials (“ASTM”) Standard ASTM D 5755-55 was developed by an EPA committee of multiple scientists, which Dr. Longo chaired.¹⁴⁹ ASTM 5755 requires use of the TEM three-step method.¹⁵⁰
- **J&J:** J&J employed the TEM three-step method for testing talc for asbestos.¹⁵¹

4. Dr. Longo published on the use of the TEM three-step method in the peer-reviewed literature.

Dr. Longo has published peer-reviewed literature on the use of the three-step TEM method to determine the presence of asbestos in multiple diverse substances.¹⁵²

¹⁴⁴ EPA AHERA, 40 CFR Ch. 1, App’x A to Subpart E of § 763 at 893, attached hereto as **Exhibit 47**.

¹⁴⁵ **Exhibit 45**, ISO 22262-2 at v.

¹⁴⁶ **Exhibit 41**, ISO 22262-1 at 1.

¹⁴⁷ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, 7/24/2019, at 483:13-23, 495:17-495:5, 508:14-509:17, 511:8-512:20, 594:14-16, 652:2-11.

¹⁴⁸ **Exhibit 45**, ISO 22262-2 at 38.

¹⁴⁹ **Exhibit 5**, Longo Hr’g Tr. 7/24/2019, 7/24/2019, at 451:4-453:22; ASTM D5755-09, attached hereto as **Exhibit 48**.

¹⁵⁰ **Exhibit 48**, ASTM D5755-09 at 1.

¹⁵¹ JNJNL61_000043150-43151, attached as **Exhibit 49**.

¹⁵² William E. Longo, et al., *Crocidolite Asbestos Fibers in Smoke from Original Kent Cigarettes*, 55 Cancer Research 2232 (1995), attached hereto as **Exhibit 50**; William E. Longo, et al., *Fiber release during the removal of asbestos-containing gaskets: a work practice simulation*, 17 Applied

Notably, these tests were used to detect asbestos in materials where it would otherwise not be suspected, such as cigarette filters, lung tissue, and vermiculite.¹⁵³ Additionally, Dr. Longo's testing of J&J' cosmetic talcum powder for asbestos was discussed in a published peer reviewed article, which reported "evidence of the causal link between asbestos, talc, and ovarian cancer and indicate[d] that asbestos is present in consumer talc products at a level sufficient to cause disease."¹⁵⁴

C. Dr. Longo strictly applied the TEM three-step testing method.

1. Step One: Morphology

Applying the EPA AHERA methodology to confirm that the morphology correlates with that of an asbestos fiber, Dr. Longo analyzed whether the structures he found in the J&J talc had an aspect ratio greater than or equal to 5:1 and a length

Occupational and Environmental Hygiene 55-62 (2002), attached as **Exhibit 51**; William M. Ewing, et al., *Zonolite Attic Insulation Exposure Studies*, 16 Int. J. Occup. Environ. Health 279 (2010), attached hereto as **Exhibit 52**; Joan E. Steffen, et al., *Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders—A Case Series*, J. Occup. and Environ. Med., Feb. 2020, 62(2) at e65-e77, attached hereto as **Exhibit 6**; **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, 7/24/2019, at 474:15-5, 488:5-489:16.

¹⁵³ See William E. Longo, et al., *Crocidolite Asbestos Fibers in Smoke from Original Kent Cigarettes*, 55 Cancer Research 2232 (1995) (asbestos in cigarette filters), attached hereto as **Exhibit 50**; William E. Longo and Victor Roggli, *Mineral Fiber Content of Lung Tissue in Patients with Environmental Exposures: Household Contacts vs. Building Occupants*, The Third Wave of Asbestos Disease: Exposure to Asbestos in Place, Annals of The New York Academy of Sciences, Vol. 643 (asbestos in lung tissue), attached as **Exhibit 53**; William M. Ewing, et al., *Zonolite Attic Insulation Exposure Studies*, 16 Int. J. Occup. Environ. Health 279 (2010) (use of the TEM three-step method to identify tremolite and actinolite asbestos in Libby, Montana vermiculite), attached hereto as **Exhibit 52**; see also **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, 7/24/2019, at 489:5-23; 490:4-491:17.

¹⁵⁴ Joan E. Steffen, et al., *Serous Ovarian Cancer Caused by Exposure to Asbestos and Fibrous Talc in Cosmetic Talc Powders—A Case Series*, J. Occup. and Environ. Med., Feb. 2020, 62(2) at e73, attached hereto as **Exhibit 6**.

greater than or equal to 0.5 micrometers.¹⁵⁵ These are the same counting rules as promulgated by ASTM and ISO.¹⁵⁶ The EPA adopted the 5:1 aspect ratio, because “[i]t is consistent with the panel of microscopists’ observations that asbestos structures have aspect ratios equal to and greater than 5:1 whereas the majority of nonasbestos structures, minerals and particles, for example, gypsum, have aspect ratios of less than 5:1.”¹⁵⁷

2. Step Two: EDXA

The next step of Dr. Longo’s peer-reviewed, published three step method is the Energy Dispersive X-ray Analysis (“EDXA”).¹⁵⁸ This allows an analyst to determine the chemistry of the fiber being examined.¹⁵⁹ The point of the EDXA analysis is to “compare spectrum profiles with profiles obtained from asbestos standards.”¹⁶⁰ “The closest match identifies and categorizes the structure.”¹⁶¹ Again, J&J does not claim that EDXA is an unreliable methodology; J&J criticizes Dr.

¹⁵⁵ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 495:5-9; **Exhibit 47**, EPA AHERA Regulations, 40 CFR Ch. 1, App’x A to Subpart E of § 763 at 871.

¹⁵⁶ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 495:5-14; 497:11-19; see James Millette, *Procedure for the Analysis of Talc for Asbestos*, 61 *The Microscope* 1, at 16 (2015) (“Comparison of the aspect ratio plots in the 1977 Bureau of Mines Circular (26) shows that a criterion of about 5:1 aspect ratio appears to be the best aspect ratio discriminator for asbestos versus non-asbestos fibers. The 5:1 aspect ratio is used in AHERA; ASTM methods D6281, D5755, D5756 and D6480; and ISO 10312 and 13794.”), attached as **Exhibit 54**.

¹⁵⁷ **Exhibit 46**, 52 Fed. Reg. 41826 (Oct. 30, 1987), at 41840.

¹⁵⁸ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 502:23-503:4; Longo-MDL_00324, attached as **Exhibit 55**.

¹⁵⁹ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 502:23-503:4.

¹⁶⁰ **Exhibit 47**, EPA AHERA, 40 CFR Ch. 1, App’x A to Subpart E of § 763 at 871.

¹⁶¹ *Id.* at 893.

Longo's *application* of this methodology because Dr. Longo did not provide the numerical results for the chemical elements.¹⁶² But no methodology requires the production of the numerical elements.

First, the EPA AHERA method does not require that the numerical value of each element is reproduced below the EDXA spectrum.¹⁶³ On the contrary, the EPA AHERA method requires a "semiquantitative comparison" with the reference spectra.¹⁶⁴ *Second*, J&J's expert Dr. Dyar conceded that she could not cite any standard requiring EDXA data formulation printouts.¹⁶⁵ *Third*, Dr. Longo's laboratory followed the precise specifications of ASTM D5755, which requires the analyst to "record at least one X-ray spectrum for each type of asbestos observed per sample. Attach the print-outs to the back of the count sheet."¹⁶⁶ The quantitative results for the chemical composition of the fibers are not required under ASTM D5755.¹⁶⁷ *Fourth*, ISO 22262-1, the method for testing talc for asbestos, does not require the analyst produce the quantitative results for the fibers' chemical composition; the analyst looks to see if the "peaks" are "comparable in ratio" to the referenced

¹⁶² ECF No. 9736-3 at 64-66.

¹⁶³ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 504:1-7.

¹⁶⁴ *Id.* at 504:13-505:6.

¹⁶⁵ **Exhibit 56**, Dyar Dep. at 124:14-131:17, 137:2-129:9.

¹⁶⁶ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 505:7-23; Longo-MDL_00878, attached as **Exhibit 57**.

¹⁶⁷ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 505:24-506:7.

exemplars.¹⁶⁸ “It is a visual comparison to the standard.”¹⁶⁹ Notably, despite extensive briefing criticizing Dr. Longo’s lack of quantification in using EDXA, J&J had *no questions* for Dr. Longo at the *Daubert* Hearing on this matter after Dr. Longo explained that such quantification is not required.

3. Step Three: SAED

The EPA AHERA requires a “visual identification of electron diffraction (ED) patterns” to confirm that a fiber is asbestos.¹⁷⁰ SAED shows a pattern of dots that reflect the arrangement of atoms of the minerals, revealing its crystal structure and accordingly its mineral type.¹⁷¹ This third step enables the analyst to distinguish between fibrous talc and anthophyllite asbestos, by tilting the fiber along the goniometer, which Dr. Longo did here.¹⁷² Again, J&J does not object that SAED is an unreliable methodology. The EPA AHERA method requires the analyst to “[v]erify the identification of the pattern by measurement or comparison of the pattern with patterns collected from standards under the same conditions.”¹⁷³ MAS followed this protocol.¹⁷⁴ ISO 22262-1 also does not require dual zone axis;¹⁷⁵ it states “[a]nalysis of laboratory samples seldom requires zone-axis measurements.”¹⁷⁶ Additionally, Dr. Longo followed the ASTM 5755 protocol for SAED, which does not require dual zone-axis

¹⁶⁸ **Exhibit 41**, ISO 22262-1 at 34; **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 506:8-11.

¹⁶⁹ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 506:16-24.

¹⁷⁰ **Exhibit 47**, EPA AHERA at 873-874, 893 (detailing patterns for chrysotile asbestos and amphibole asbestos); **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 507:3-15.

¹⁷¹ Longo-MDL_00325 (Tremolite Diffraction at 50cm), attached as **Exhibit 58**.

¹⁷² **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 508:14-509:17.

¹⁷³ **Exhibit 44**, EPA AHERA, p. 899.

¹⁷⁴ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 508:5-13.

¹⁷⁵ *Id.* at 509:10-17.

¹⁷⁶ **Exhibit 41**, ISO 22262-1 at 64.

measurements.¹⁷⁷ Finally, J&J's own protocols for measurement by SAED do not require zone-axis measurements.¹⁷⁸

D. There were no flaws in Dr. Longo's application of the reliable TEM methodologies, let alone major flaws warranting exclusion.

1. J&J's objections to the application of the TEM three-step process does not warrant exclusion.

J&J does not dispute that heavy liquid separation or the TEM three-step process are reliable methodologies. Thus, the evidence before this Court is that Dr. Longo used methods that have been tested and subjected to peer review and publication, that are governed by controlling standards, and that enjoy acceptance within the scientific community. J&J's criticisms as to the *application* of these reliable methodologies have no merit, and certainly are not sufficient to warrant exclusion.¹⁷⁹

Heavy Liquid Separation: J&J does not object to Dr. Longo's use of the heavy liquid separation method, nor to his application of this method.

TEM Three-Part Test: J&J's objections to the application of the TEM three-part test are without merit. For determination of morphology ("counting"), J&J erroneously argues that Dr. Longo only used the counting criteria to determine if a fiber is asbestos, and thus it was "overinclusive."¹⁸⁰ On the contrary, Dr. Longo testified that

¹⁷⁷ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 510:23-511:7.

¹⁷⁸ *Id.* at 513:12-514:3; *see also* JNJNL61_000043153, attached as **Exhibit 49**, and JNJNL61_000005038, attached as **Exhibit 59**.

¹⁷⁹ *See, e.g. In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 767 (district court erred in excluding medical opinion, even though the experts conclusion may have been incorrect, where the methodology followed was "reasonably reliable.").

¹⁸⁰ ECF No. 9736-3 at 34.

he first eliminated non-asbestos fibers that did not meet the requisite morphological criteria, and then used SAED and EDXA to confirm they are asbestos. Additionally, no procedure requires an analyst to provide numerical chemical numbers below the graph, as J&J's expert Dr. Dyer concedes.

2. J&J's remaining criticisms all go to the weight, not the admissibility of the evidence.

a. No methodology requires the analyst to ascertain the way in which the fibers were formed to classify them as asbestos.

J&J argues that Dr. Longo did not determine the manner in which the fibers were formed, such that Dr. Longo could say that the fibers are "asbestiform."¹⁸¹ But J&J appears to willfully ignore that the methodologies employed by Dr. Longo provide that if a fiber meets the requisite criteria, it is asbestos. The EPA stated that

It is the position of EPA, the U.S. Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease, Registry and National Institute for Occupational Safety and Health, and the American Thoracic Society, among others, that microscopic structures of amphibole and serpentine materials that are asbestiform and meet the size definition of PCM fibers should be counted as asbestos regardless of the manner in which they were formed.¹⁸²

Dr. Longo testified that he strictly adhered to ISO22262-1 protocol for analysis to determine if there is amphibole asbestos in J&J talc.¹⁸³ The ISO standard explicitly

¹⁸¹ ECF No. 9736-3 at 5-6.

¹⁸² **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 661:18-662:25, 647:1-12; Resp. to the Nov. 2005 Nat'l Stone, Sand & Gravel Assoc. Rep. Prepared by the R.J. Lee Group, Inc., "Evaluation of EPA's Analytical Data from the El Dorado Hills Asbestos Evaluation Project" (Apr. 20, 2006), attached as **Exhibit 60**.

¹⁸³ **Exhibit 7**, Longo Hr'g Tr. 7/24/2019, at 530:18-533:9; 531:18-532:15.

provides that using this method enables the analysis to determine whether the fibers are “asbestiform.”¹⁸⁴

b. The fiber versus bundle argument is a strawman.

J&J attempts to create a strawman by arguing that “Drs. Longo and Rigler’s identification of ‘bundles’ is fundamental to their visual TEM analysis,” and because there were conflicts in the analysts’ classification of fiber versus bundle, Dr. Longo cannot reliably conclude that a fiber is asbestos.¹⁸⁵ But nowhere does the TEM three-step method require a distinction between fibers versus bundles to determine whether a fiber is “asbestiform.”

First, the generally accepted TEM three-step method is capable of classifying a single fiber as asbestos.¹⁸⁶ Under the published TEM methods, both fibers and bundles are asbestos.¹⁸⁷ *Second*, the “test” that J&J criticizes was not designed to discern between fibers and bundles. Dr. Longo explained that “[t]his test was only designed to determine the counting statistics. We never asked the analysts to do a fiber bundle agreement study.”¹⁸⁸ *Third*, there was 72.2% agreement as to whether

¹⁸⁴ **Exhibit 41**, ISO 22262-1 at 22-23.

¹⁸⁵ ECF No. 9736-3 at 40.

¹⁸⁶ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 520:1-23; **Exhibit 45**, ISO 22262-2 at 7 (“The limit of quantification using this part of ISO 22262 is defined as the detection and identification of one fibre or fibre bundle.”).

¹⁸⁷ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 524:1-20; **Exhibit 47**, EPA AHERA at 871; **Exhibit 48**, ASTM D5755-09 at 2, 8.

¹⁸⁸ **Exhibit 7**, Longo Hr’g Tr. 7/24/2019, at 603:16-24.

tremolite structures were fibers or bundles.¹⁸⁹ For anthophyllite, there was 83.7% agreement. **Finally**, Dr. Longo testified that every year his laboratory is subject to a NVLAP audit testing on the issues of fibers and bundles, and for the 2017 testing performed by NVLAP, the level of consistency in terms of validation of the analysts that tested J&J's talc for asbestos to accurately determine whether the asbestos structure is a fiber or a bundle was above 95 percent agreement.¹⁹⁰ For the previous three years, 2016, 2015, and 2014, they were all above 95 percent agreement.¹⁹¹

In sum, J&J's only complaints as to Dr. Longo's testing for the presence of asbestos in its talc apply to the **application** of what J&J admits are reliable methodologies.¹⁹² None of J&J's alleged "errors" in application (which Plaintiffs dispute) were capable of skewing the methodology itself. Dr. Longo thus properly determined by morphology, chemistry, and crystal composition that certain fibers were asbestos.

II. Dr. Longo's Polarized Light Microscopy ("PLM") opinions are the result of the reliable application of well-accepted, reproducible methodologies.

A. Combining two scientifically accepted methodologies—PLM and the heavy liquid separation sample preparation method ("HLS")—Dr. Longo repeatedly found chrysotile asbestos.

¹⁸⁹ *Id.* at 524:21-526:19.

¹⁹⁰ *Id.* at 526:20-25; 668:3-25.

¹⁹¹ *Id.*

¹⁹² "An alleged error in the application of a reliable methodology should provide the basis for exclusion of that opinion only if the error negates the basis for the reliability of the principle itself." *United States v. Martinez*, 3 F.3d 1191, 1198 (8th Cir. 1993).

For more than 200 years, PLM “has been used by mineralogists to identify minerals.”¹⁹³ Using PLM, an analyst can observe several optical properties that can be used to differentiate one mineral from another.¹⁹⁴ Those properties include indices of refraction (“RI”), birefringence, sign of elongation, and size, among others.¹⁹⁵

RI is regarded as one of the “most important optical properties” of non-opaque minerals, such as asbestos.¹⁹⁶ It is the “sign and magnitude of the match/mismatch between a solid and its surrounding liquid[.]”¹⁹⁷ To measure this, there are three methods that can be used.¹⁹⁸ According to J&J’s expert, Dr. Su, “[o]nly the dispersion staining (DS) can meet the . . . specific needs for the routine PLM analysis of bulk asbestos samples in commercial environmental laboratories.”¹⁹⁹

Using dispersion staining, the RI is determined by observing the color produced when the sample is immersed in an RI liquid.²⁰⁰ The color observed at the edge of the particle corresponds with a wavelength.²⁰¹

¹⁹³ **Exhibit 61**, 5/3/2024 Wylie Report, pg. 4.

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*; see also **Exhibit 62**, Dr. Shu-Chun Su, “The Dispersion Staining Technique and its Application to Measuring Refractive Indices of Non-opaque Materials, with Emphasis on Asbestos Analysis,” *The Microscope* (2022), pg. 51 (hereinafter “Su (2022)”).

¹⁹⁶ **Exhibit 62**, Su (2022), pg. 52.

¹⁹⁷ *Id.*, pg. 53.

¹⁹⁸ *Id.*, pg. 53.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *Id.*

Matching Wavelength λ_m , nm	Particle Edge Colors ²	
	Annular Stop ⁴	Central Stop ⁵
<340	Black violet	White
<400	Dark violet	Pale yellow
430	Violet	Yellow
455	Blue	Golden yellow
485	Blue-green	Orange
520	Green	Red purple

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After confirming the temperature of the liquid and observing the color of the particle edge in both the parallel (gamma) and perpendicular (alpha) orientations, the analyst will match the wavelengths in both orientations with the corresponding refractive indices using standardized charts, such as the one below.²⁰³

λ_m (nm)	α						
	17° C	19° C	21° C	23° C	25° C	27° C	29° C
300	1.648	1.647	1.646	1.645	1.644	1.643	1.642
320	1.627	1.626	1.625	1.624	1.623	1.622	1.621
340	1.612	1.611	1.610	1.609	1.608	1.607	1.606
360	1.601	1.600	1.599	1.598	1.597	1.596	1.595
380	1.592	1.591	1.590	1.589	1.588	1.587	1.586
400	1.585	1.584	1.583	1.582	1.581	1.580	1.579
420	1.579	1.578	1.577	1.576	1.575	1.574	1.573

Once that is done for both the parallel and perpendicular orientations, the alpha and gamma RI values for the particle under consideration can be recorded and compared to standards for chrysotile.²⁰⁴ In doing that, the analyst can choose from several standards, which according to the National Institute of Standards & Technology (“NIST”) can vary based on geographic region and acid/heat treatment.²⁰⁵

²⁰² *Id.*, pg. 66.

²⁰³ *Id.*, pg. 56-57.

²⁰⁴ **Exhibit 41**, ISO 22262-1, pgs. 33-34; **Exhibit 63**, EPA 600, pg. 26.

²⁰⁵ **Exhibit 64**, NIST, pg. 1.

Using the gamma and alpha RI values, a sample's birefringence can be calculated by subtracting the lowest value for alpha from the highest gamma value. According to the EPA, the birefringence of chrysotile ranges from 0.004 to 0.007.²⁰⁶ The birefringence of talc is "about 10 times higher," with a range that on the low end,²⁰⁷ is reported to start at 0.04 to 0.045.²⁰⁸

While PLM offers several advantages over other methods, such as its ability to inspect a larger sample size, it is not without its limitations with one being its limited sensitivity.²⁰⁹ To overcome that limitation, it is necessary to examine larger amounts of the sample to detect chrysotile in talc.²¹⁰ To do that, the Colorado School of Mines developed a procedure to detect chrysotile at a "level of 10 ppm or less" in talc using HLS.²¹¹ That process involves centrifuging the sample in a heavy liquid to separate the chrysotile from the talc and concentrate it.²¹²

Based on the approach developed by the Colorado School of Mines, Dr. Longo used HLS to increase the sensitivity of the PLM testing.²¹³ He then followed

²⁰⁶ **Exhibit 63**, EPA 600, pg. 26.

²⁰⁷ **Exhibit 65**, 7/11/20224 Su Tr. at 85:4-11, 87:16-21.

²⁰⁸ *Id.* at 87:16-17; *see also id.* at 85:4-11 ("Q. The birefringence associated with talc is generally higher than this? A. Much higher."), 87:16-21 (testifying that the birefringence for talc is "about 10 times higher than the chrysotile").

²⁰⁹ **Exhibit 1**, White Paper at 16-17.

²¹⁰ **Exhibit 66**, CSM, pg. 3.

²¹¹ *Id.*, pg. 6.

²¹² *Id.*

²¹³ **Exhibit 27**, Longo Fourth Supplemental MDL Report 4/29/24, at 11; **Exhibit 67**, Longo Tr. 5/29/2024, at 184:2-25 (describing use of HLS).

the methods outlined in ISO 22262-1 and EPA600/R-93/116 to analyze the samples for chrysotile, which he had not been done before.²¹⁴ Doing that, and comparing the samples to standards for Calidria chrysotile, which “can have slightly higher refractive indices than the more common chrysotile,”²¹⁵ Dr. Longo identified chrysotile in 40 of the 43 samples testing based on the morphology of the particles, as well as their RI and birefringence values.²¹⁶

B. Chief Judge Wolfson’s opinion on PLM testing addressed a different PLM testing method than what Dr. Longo presently uses.

In asking this Court to exclude Dr. Longo’s opinions about the PLM/HLS methodology he now employs, J&J portrays that methodology as something entirely new. It is not. As Dr. Longo readily admits, what he did here in testing J&J’s talc for asbestos is never going to be called the “Longo method.”²¹⁷ The reason for this is simple. Neither PLM nor HLS are new. Both have been used now for decades. And while Dr. Longo has combined these methodologies to test J&J’s talc for chrysotile, even that is not new. It is merely the application of two longstanding and widely accepted methodologies in combination with each other.²¹⁸

²¹⁴ **Exhibit 67**, Longo Tr. 5/29/2024, at 182:21-183:2.

²¹⁵ **Exhibit 68**, 9/6/2024 Gunter Tr., at 309:5-15.

²¹⁶ **Exhibit 27**, Longo Fourth Supplemental MDL Report 4/29/24, at 2, 11-15; **Exhibit 67**, Longo Tr. 5/29/2024, at 221:9-16.

²¹⁷ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 150:8-11.

²¹⁸ *Id.* at 132:10-21 (“There’s hundreds and hundreds of papers out there published about using” HLS and while MAS is “going after a different mineral that people haven’t gone after in the past,” it is “not a novel analytical method”), 138:23-139:2 (“The use of [HLS] is really well established to separate out minerals, to separate out all kinds of stuff, anything that has two densities.”).

As Dr. Longo notes in his Fourth Supplemental Report, MAS began using PLM together with HLS to test J&J's talc for chrysotile after Judge Wolfson issued the April 27, 2020 Opinion. Judge Wolfson's determination to exclude Dr. Longo's former PLM methodology (without HLS) thus concerned a different methodology than the one now employed.²¹⁹ To be clear, Judge Wolfson did not consider the admissibility of Dr. Longo's current PLM/HLS methodology. J&J refuses to concede that Judge Wolfson did not consider the PLM/HLS methodology Dr. Longo now employs. Instead, J&J asks this Court to extend that decision to the PLM/HLS methodology used today without regard to the differences between the two methodologies.²²⁰ Simply stated, Judge Wolfson's reasoning at the time of the prior *Daubert* hearing does not apply to the methodology at issue now.

J&J first contends that Dr. Longo should have followed the methodology outlined in ISO 22262-2.²²¹ That misunderstands ISO 22262 and its subparts. "ISO 22262-1 specifies procedures for collection of samples and qualitative analysis of commercial bulk materials for the presence of asbestos."²²² It also details procedures "for identification of asbestos by polarized light microscopy and dispersion

²¹⁹ **Exhibit 27**, Longo Fourth Supplemental MDL Report, pg. 2.

²²⁰ Dkt. 33012-2, pgs. 20-21.

²²¹ Dkt. 33012-2, pg. 20.

²²² **Exhibit 45**, ISO 22262-2, pg. 6.

staining.”²²³ ISO 22262-2 meanwhile serves as a compliment to ISO 22262-1.²²⁴ In fact, according to the International Organization for Standardization (“ISO”), the application of ISO 22262-1 is “indispensable” to ISO 22262-2.²²⁵ As ISO further explains, ISO 22262-2 “is primarily intended for application to samples in which asbestos has been identified at estimated mass fractions lower than approximately 5% by weight.”²²⁶ But that does not make ISO 22262-2 “necessary” when the mass fraction of a sample is less than 5% by weight.²²⁷

Contrary to J&J’s argument here, ISO explains that “[q]uantification of asbestos beyond the estimate of mass fraction achieved using ISO 22262-1 may not be necessary, depending on the applicable regulatory limit for definition of an asbestos-containing material, the variety of asbestos identified, and whether the sample can be recognized as a manufactured product.”²²⁸ As ISO explains, if chrysotile, amosite, crocidolite, or anthophyllite is detected in a product and the definition requires only a “presence of asbestos,” then “no further quantification is necessary.”²²⁹ In that case, ISO 22262-2 makes clear that the procedures it describes need not be followed as a “more precise and significantly more expensive

²²³ **Exhibit 41**, ISO 22262-1, pg. 9.

²²⁴ **Exhibit 45**, ISO 22262-2, pg. 6 (“A prerequisite for use of this part of ISO 22262 and subsequent parts of ISO 22262 is that the same shall have been examined [under] ISO 22262-1.”)

²²⁵ *Id.* at pg. 7.

²²⁶ *Id.* at pg. 7.

²²⁷ *Id.* at pg. 12.

²²⁸ *Id.* at pg. 12.

²²⁹ *Id.* at pgs. 12-13.

determination of the asbestos mass fraction will neither change the regulatory status of the asbestos-containing material[.]”²³⁰

J&J’s argument here also overlooks that ISO 22262-2 lacks procedures for identifying chrysotile in talc.²³¹ ISO 22262-2 states that “[a]lthough separation of chrysotile from talc by centrifugation in a heavy liquid is theoretically possible, in general it is not a practical technique.”²³² This is because “chrysotile may be more problematic to separate than the amphiboles because its density is similar to (or less than) the density of talc.”²³³ But as Dr. Longo notes, separating chrysotile out from talc, while not practical, “can be done.”²³⁴ As he explains, a “lot of work had to be done” to use HLS to test talc for chrysotile, which he “wouldn’t even have tried if we didn’t come across Johnson & Johnson’s [HLS Report] from the Colorado School of Mines.”²³⁵ Elaborating on that point, Dr. Longo testified that until he came into possession of the Colorado School of Mine’s 1973 HLS procedure, the “overwhelming feeling [was] that you could not use heavy liquid density separation to get chrysotile out of cosmetic talc” because chrysotile “can be anywhere from 2.55 grams per centimeter cubed, where talc may be 2.60 or 2.66[.]”²³⁶ As he

²³⁰ *Id.* at pg. 12.

²³¹ *Id.* at pg. 35.

²³² *Id.* at pg. 35.

²³³ **Exhibit 1**, White Paper at 111.

²³⁴ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 105:13-106:2.

²³⁵ **Exhibit 67**, Longo Tr. 5/29/2024, at 40:15-22.

²³⁶ *Id.* at 184:5-13.

explained, the Colorado School of Mines “showed it was possible to separate out chrysotile from talc.”²³⁷ Based on that methodology, MAS has “validated a detection limit of approximately 0.0001 percent by weight fibers per gram of talc.”²³⁸

While Dr. Longo acknowledged there were some differences from what he did and what the Colorado School of Mines published, such as the use of a medium with a density of 2.65 g/cc rather than one that was less than 2.65 g/cc, he followed the same basic approach and had just “tweak[ed] it.”²³⁹ He is not alone in this regard as others such as R.C. Reynolds Jr. and R.J. Lee (Dr. Sanchez’s employer and the primary laboratory used by J&J for the last decade) have used various HLS protocols.²⁴⁰ Those “slight” differences do not undermine the reliability of Dr. Longo’s methodology. To the contrary, the Third Circuit has explained that if an “expert uses a methodology only slightly different from a clearly reliable methodology, the court should be more likely to accept the altered methodology than if it was evaluating the altered methodology as an original matter.”²⁴¹

²³⁷ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 136:2-12.

²³⁸ *Id.* at 149:14-19.

²³⁹ *Id.* at 147:17-150:11.

²⁴⁰ As Dr. Longo explains in his Fourth Supplemental Report, several HLS protocols have been used by other researchers in the years since the Colorado School of Mines published its paper, each of which, used “slightly different density liquids and different centrifuge times . . . in an effort to increase analytical sensitivity.” **Exhibit 27**, pg. 8; *See also* **Exhibit 44**, Memo from R. C. Reynolds, Jr. to Windsor Minerals Inc. (Mar. 1974); **Exhibit 70**, RJ Lee Std. Operating Procedure.

²⁴¹ *Paoli*, 35 F.3d at 745 n. 14.

None of J&J's experts have critiqued Dr. Longo's HLS methodology.^{242, 243}

This Court can readily find that in following the HLS methodology outlined by the Colorado School of Mines, Dr. Longo has followed an accepted and reliable methodology designed to increase the sensitivity of PLM analysis.

J&J also claims that that the PLM/HLS methodology should be excluded because Chief Judge Wolfson had found that his previous PLM methodology was "replete with subjectivity and reproducibility problems."²⁴⁴ Despite disagreement with the earlier decision, it is no longer applicable. J&J indeed quotes Judge Wolfson's statement that the "analysis was subjective because 'the quantity of asbestos in the samples determined by visual examination 'based on past standards, based on petrographic that show what the various percentages are' and that those "standards (weight percentages) were generated by MAS and were not produced to

²⁴² **Exhibit 71**, Wylie Dep. 6/24/2024, at 104:9-16 (Dr. Wylie: "I do not intend to criticize" the use of HLS in the analysis of whether there is chrysotile in talc).

²⁴³ In attempting to criticize Dr. Longo's HLS methodology, Dr. Su wrote that the HLS procedure "produced a series of extremely inconsistent light fractions ranging from 13.4% to 24.2%." **Exhibit 72**, Su Report 5/21/2024, pg. 11. And then noting that "Baby Powder samples consist[ed] of 99% talcum powder," Dr. Su asked "how possible is the light fraction more than 1%?" *Id.* Answering that question, he said that "[i]t is beyond comprehension that those ridiculous two-digit light fractions results did not make MAS realize something was grossly wrong with each and every sample preparation procedure that it tried over the course of five years." *Id.*, pgs. 10-11. When asked about the basis for his belief that Baby Powder is 99.9% talcum powder, Dr. Su testified that "because MAS didn't report the amount of nickel or carbonates or whatever else might be present," he "took that to mean that it was chrysotile and talc and nothing else." **Exhibit 73**, Su Dep. 7/18/2024, at 60:2-6. Dr. Su's conclusion that MAS "was grossly wrong" was premised on just an assumption. This therefore is not a valid critique of Dr. Longo's HLS methodology.

²⁴⁴ Dkt. 33012-2, pg. 21.

Defendants,’ which made ‘replication of Dr. Longo’s testing difficult.’”²⁴⁵ But as J&J’s own expert, Dr. Wylie admits, Dr. Longo’s PLM/HLS “method produced enough raw data for [her] to determine whether the talc sample contained chrysotile.”²⁴⁶

Lastly, J&J states that “Judge Wolfson recognized that Dr. Longo’s PLM findings had not been reproduced by others, despite at least one attempt.”²⁴⁷ J&J contends that Dr. Steven Compton tested eighteen Chinese talc or samples, which Dr. Longo had tested and had found asbestos by using PLM.²⁴⁸ J&J contends that because Dr. Compton found no chrysotile in any of those samples, Dr. Longo’s PLM results are questionable as Dr. Compton used “TEM, which is the more sensitive microscope.”²⁴⁹ While the advantage of TEM is that it is more sensitive, the disadvantage in using testing samples is the low mass fraction rates.²⁵⁰ Dr. Compton’s use of a different methodology which has its own limitations, and for an assay in which PLM is better suited, in no way casts doubt on Dr. Longo’s current PLM/HLS methodology. In making this argument, J&J asks this Court to focus on the experts’ ultimate conclusions, rather than on their methodologies, contrary to the

²⁴⁵ Dkt. 33012-2, pgs. 21-22 (quoting *In re J&J*, 509 F. Supp. 3d at 155).

²⁴⁶ **Exhibit 71**, Wylie Dep. 6/24/2024, at 33:10-15, 34:12-23, 44:6-20.

²⁴⁷ Dkt. 33012-2, pg. 23.

²⁴⁸ *Id.*, pg. 24.

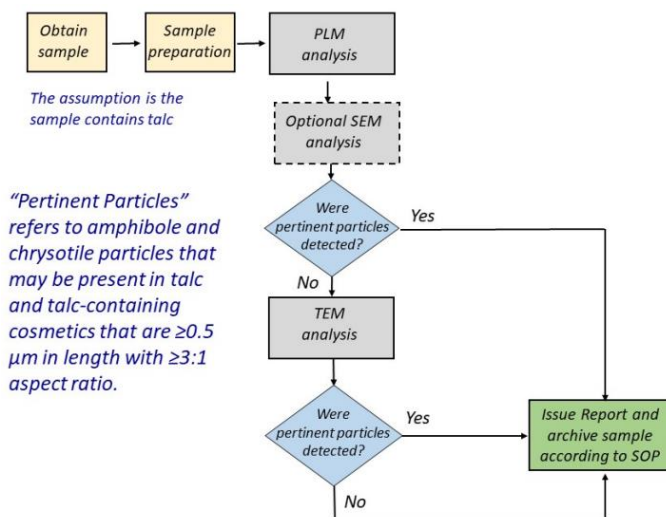
²⁴⁹ *Id.*

²⁵⁰ **Exhibit 1**, White Paper at 11 (“Whereas TEM offers the advantage of resolving short and thin particles, only a relatively small amount of sample can be analyzed. PLM, by contrast, offers the advantage of inspecting a larger sample size, albeit at much reduced resolution.”).

Third Circuit’s warning that “*Daubert* requires the judge's admissibility decision to focus not on the expert's conclusions but on his or her principles and methodology.”²⁵¹

J&J’s insinuation that Dr. Longo’s PLM methodology is unreliable because he did not also test the samples by TEM is wrong for two additional reasons.

First, J&J’s argument that Dr. Longo should have also tested those samples using TEM is contrary to accepted standards. According to the “IWGACP,” if the PLM analysis detects asbestos, “the analyst should conclude that the sample contains these particles (‘Yes’) and report the observation (record data).”²⁵² It is only if the “PLM results are negative (‘No’), electron microscopy should be performed.”²⁵³



²⁵¹ *Paoli*, 35 F.3d at 746.

²⁵² **Exhibit 1**, White Paper at 20, 22 (citing Rohl and Langer, 1974; Millette, 2015; Block, 2014) (noting that many experts agree that TEM should be used if the “findings of PLM are negative”).

²⁵³ *Id.* at 22.

As Dr. Longo found asbestos using PLM, he did not need to confirm those results by TEM. This is because the concern over PLM is not that it will produce false positives, but false negatives.²⁵⁴ Because PLM is prone to returning false *negative* results, that fact provides good reason to suspect and discount negative results. That shortcoming, however, provides no reason to discount *positive* test results such as those found by Dr. Longo using PLM. J&J's insistence on a symmetric response to a test prone to false *negatives* is thus irrational and contrary to the recommendations by other experts and groups such as the IWGACP.

Second, while Dr. Longo has not run the samples he tested using PLM/HLS through TEM, other samples tested using TEM have been found to contain asbestos. Some of those tests date back decades.²⁵⁵ Others are more recent, such as AMA Analytical Service, Inc.'s 2019 report for the FDA.²⁵⁶ As those TEM tests disprove J&J's position that its talcum powder has always been asbestos free, they validate Dr. Longo's PLM/HLS methodology and its results.

For all these reasons, J&J's reliance on Judge Wolfson's prior opinion about Dr. Longo's prior methodology is misplaced.

²⁵⁴ **Exhibit 1**, White Paper at 68 (describing FDA study of the analysis of 52 cosmetic products that negative for chrysotile when using PLM, nine of which afterward tested positive for tremolite or chrysotile by TEM and on retesting again three more times, seven of those samples still tested negative using PLM).

²⁵⁵ **Exhibit 3**, Hopkins 28.

²⁵⁶ **Exhibit 74**, AMA Analytical Service, Inc.'s report for the FDA, outlining its identification of chrysotile asbestos by TEM.

C. Each of Rule 702’s factors support admitting Dr. Longo’s PLM/HLS opinions.

Rule 702’s factors support admitting Dr. Longo’s PLM opinions. Those factors “may include (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique’s operations; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witnesses testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.”²⁵⁷ These factors “are neither exhaustive nor applicable in every case.”²⁵⁸

Testable Hypothesis – J&J rather incredibly claims that Dr. Longo’s methodology lacks a testable hypothesis.²⁵⁹ His hypothesis—that asbestos can be found in J&J’s talc—is testable. It is not one in which “the only person capable of testing or falsifying the hypothesis is the creator of the methodology.”²⁶⁰ To be sure, J&J has offered three experts to test that hypothesis. Proof that it is testable, is evidenced by the testimony of one of them, Dr. Wylie, who testified that “Dr.

²⁵⁷ *Pineda*, 520 F.3d at 247-48 (citing *Paoli*, 35 F.3d at 742 n.8).

²⁵⁸ *Id.* at 248 (quoting *Kannankeril v. Terminix Int’l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)).

²⁵⁹ Dkt. 33012-2, pg. 27.

²⁶⁰ *In re TMI Litig.*, 193 F.3d 613, 703 n.144 (3d Cir. 1999).

Longo's method produced enough raw data for [her] to determine whether the talc sample contained chrysotile."²⁶¹

Peer Review – Taking a narrow view of both Dr. Longo's methodologies and what it means for a methodology to be peer-reviewed, J&J argues that Dr. Longo's methodologies have not been peer reviewed simply because Dr. Longo has not published a paper about them. The error in J&J's argument begins with its incessant focus on Dr. Longo's conclusions rather than the PLM/HLS methodologies, both of which are time-tested and well-accepted. And crucially, Dr. Longo was not the first to use PLM and HLS together to detect the presence of chrysotile and tremolite in talc. The credit for that innovation belongs to the Colorado School of Mines in its work for J&J. And giving credit where its due, the Colorado School of Mines noted in its 1973 report for J&J that the methods described therein "have evolved over a period of time, with the aid of suggestions from many individuals, and are frequently subjected to review."²⁶² That the Colorado School of Mines and others, which Dr. Longo credits in his report, have used and peer reviewed the use of PLM and HLS strengthens the reliability of Dr. Longo's use of those methodologies.²⁶³ Other aspects of Dr. Longo's methodology have also been reviewed, such as his findings

²⁶¹ **Exhibit 71**, Wylie Dep. 6/24/2024, at 33:10-15, 34:12-23, 44:6-20.

²⁶² **Exhibit 66**, 1973 CSM Protocol, pg. 3.

²⁶³ *See Ruiz-Troche v. Pepsi Cola of Puerto Rick Bottling Co.*, 161 F.3d 77, 84 (1st Cir. 1998).

on the refractive indices of Calidria chrysotile, which Dr. Gunter, one of J&J's own experts, confirmed after testing samples he received from Dr. Longo.²⁶⁴

Known or Potential Error Rate – J&J portrays Dr. Longo's work as having no known or potential rate of error on the one hand.²⁶⁵ While on the other, J&J notes that Dr. Longo has estimated that the error rate is 0.005%.²⁶⁶ Due to this contradiction, J&J tries to distinguish between the known error rate for PLM generally and for PLM testing of chrysotile.²⁶⁷ It however offers no argument or authority for distinguishing between the two. And tellingly, none of J&J's experts offered an opinion on the error rate for their own testing; a particularly curious omission given that PLM testing of chrysotile asbestos is prone to false negatives.²⁶⁸

Standards Controlling the Technique's Operations – J&J claims that because Dr. Longo is continuing to refine and improve the HLS methodology, no standards control the technique's operations. Dr. Longo testified that he is "not sure we have the exact right recipe for the most – the most efficient way to extract the

²⁶⁴ **Exhibit 75**, Longo Dep. 10/3/2022, at 606:13-21; **Exhibit 68**, Gunter Dep. 9/6/2024, at 309:5-15 ("Q... 'Calidria chrysotile can have slightly higher refractive indices than the more common chrysotile and, thus, produces CSDS colors that range from bluish to golden yellow in a 1.550 liquid.' Did I read that correctly? A. Yes. Q. And is that an opinion that you came to based on the analytical work you did on the Calidria RG144 and SG210 samples that Dr. Longo sent? A. Yes.").

²⁶⁵ Dkt. 33012-2, pg. 28.

²⁶⁶ Dkt. 33012-2, pg. 22. Dr. Longo has also testified that MAS has "validated the detection limit of approximately 0.0001 percent by weight fibers per gram of talc." **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 149:14-19.

²⁶⁷ Dkt. 33012-2, pg. 22.

²⁶⁸ **Exhibit 1**, White Paper at 20, 22, 68.

chrysotile out of the talc.”²⁶⁹ That is the mark of good science—and scientist—and not evidence that no standards control the operations of MAS’s PLM/HLS testing. And perhaps more critically, there is a difference between not having standards and not publishing them. In both his reports and testimony, Dr. Longo has described the standards applied to MAS’s PLM/HLS testing.^{270, 271}

Generally Accepted Methodologies Accepted as Reliable – Again, in arguing that Dr. Longo’s methodologies are not generally accepted, J&J confuses the methodologies—PLM and HLS—with the results it does not like. J&J’s argument is nonsensical given that J&J’s own experts used PLM to test J&J’s talc for chrysotile.²⁷² And while none of J&J’s experts in this case, unlike the Colorado School of Mines, used HLS in testing J&J’s talc, none of them have challenged Dr. Longo’s use of HLS to improve PLM’s detection limits. It bears emphasis that the IWGACP has suggested that while HLS is not a commercially practical technique, it is not an impossible one. While J&J disputes the results Dr. Longo obtained from

²⁶⁹ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 74:11-17.

²⁷⁰ **Exhibit 76**, Longo 2/28/23 Valdez M71614 Report, pgs. 4-8.

²⁷¹ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 146:5-149:6.

²⁷² Dr. Wylie testified that in testing two samples of J&J’s talc, the results of which, she did not retain, she used PLM. **Exhibit 71**, Wylie Dep. 6/24/2024, at 10:16-13:9. Despite the known propensity of PLM to produce false negatives, Dr. Wylie did not conduct a TEM analysis of the samples she tested. *Id.* at 14:12-14.

using these methodologies, that goes to credibility and weight, a question for the factfinder to resolve, not the Court.²⁷³

Qualifications of the Expert Witness – According to Judge Wolfson, “[t]here is no dispute that Dr. Longo is qualified to testify as an expert on the issue of whether the subject talc products contain asbestos.”²⁷⁴

Non-Judicial Uses – As previously stated, credit for using PLM and HLS together to test talc for asbestos belongs to the Colorado School of Mines in the work that it did for J&J. Because the Colorado School of Mines developed this methodology 51 years ago, J&J’s argument that the PLM/HLS methodology was developed for talc litigation blinks at reality.

D. There were no flaws in Dr. Longo’s application of the reliable PLM methodologies, let alone major flaws warranting exclusion.

Contrary to generally accepted methodologies for PLM testing, including ISO 22262-1, J&J levels several unfounded accusations at Dr. Longo and his identification of chrysotile asbestos based on its refractive indices, which are determined by reference to the color of the parties at their edges according to ISO 22262-1.²⁷⁵

²⁷³ *In re: Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, 2024 WL 65132, at *3 (citing *Kannankeril*, 128 F.3d at 810).

²⁷⁴ *J&J*, 509 F. Supp. 3d at 147.

²⁷⁵ **Exhibit 41**, ISO 22262-1, pg. 29.

J&J begins by insinuating that Dr. Longo could not have found chrysotile because it “should generally appear purple in parallel[.]”²⁷⁶ J&J then presents an image of chrysotile from ISO 22262-1 and implies that it is representative of all chrysotile.²⁷⁷ That image of course is not representative of all chrysotile samples; it is an image of chrysotile from one source in Canada. While that source of chrysotile is the subject of the NIST Standard Reference Material (“SRM”) 1866b, there are forms of chrysotile that exhibit different characteristics. As the National Institute of Standards & Technology states in its Certificate for Standard Reference Material 1866b, “various conditions, such as geographic origin or acid/heat treatment of the asbestos, could cause the optical properties of the asbestos in bulk insulation samples to vary considerably from the materials comprising this SRM.”²⁷⁸ Even J&J’s expert, Dr. Su, has acknowledged that “there are chrysotile minerals whose RIs are significantly higher than those of the standard chrysotile from the NIST SRM 1866 set.”²⁷⁹ During his deposition, Dr. Su admitted that “chrysotile is a family of minerals [that] depending on where it comes from may have a different refractive index than chrysotile from another place in the world.”²⁸⁰ And thus, according Dr. Su, chrysotile

²⁷⁶ Dkt. 33012-2, pgs. 30-31.

²⁷⁷ *Id.*, pg. 31 (citing ISO 22262-1, pg. 43).

²⁷⁸ **Exhibit 64**, NIST 1866B Standard, pg. 1.

²⁷⁹ **Exhibit 62**, Su (2022), at p.56.

²⁸⁰ **Exhibit 65**, Su Dep. 7/11/2024, at 69:12-16.

“taken from Canada . . . may have a different refractive index than chrysotile taken from somewhere else[.]”^{281, 282}

Because chrysotile from other regions may exhibit different characteristics, Dr. Longo evaluated Calidria chrysotile,²⁸³ which “does not produce the ‘magenta’ CSDS color, but instead has variations of the yellow-gold in the 1.550 RI fluid.”²⁸⁴ J&J’s long-time expert Dr. Gunter has similarly evaluated Calidria chrysotile and reported that “Calidria chrysotile can have slightly higher refractive indices than the more common chrysotile and, thus, produces CSDS colors that range from bluish to golden yellow in a 1.550 liquid.”²⁸⁵

Aside from ignoring the natural variation in chrysotile, J&J attempts to cast unnecessary doubt on Dr. Longo’s identification of the colors of the particles in parallel and perpendicular orientations. J&J attempts to do this in a number of ways, all flawed. Pointing to a copy of an image of a particle in MAS sample M71614-001-001, J&J quotes Dr. Longo as describing this particle as “brownish gold” and

²⁸¹ *Id.* at 69:17-18.

²⁸² Addressing Calidria chrysotile specifically, Dr. Wylie testified that the “optical data MAS has presented for the Coalinga chrysotile is not for chrysotile at all, but rather one of the other minerals present, such as pyroaurite and/or brucite.” **Exhibit 61**, Wylie Report 5/3/2024, pg. 32. While Dr. Wylie claims to have based this conclusion on her own testing of Coalinga chrysotile, she admitted that she relied on a sample from 1978 in the University of Maryland’s collection. **Exhibit 71**, Wylie Dep. 6/24/2024, at 110:8-11. She could not however say whether the 1978 sample she tested resembled the one Dr. Longo tested from 1995 given that she “of course” does not know given that “the deposit could vary to some extent depending upon where they were mining it.” *Id.* at 64:18-23.

²⁸³ **Exhibit 27**, Longo Fourth Supplemental MDL Report 4/29/24, at 12.

²⁸⁴ **Exhibit 77**, Longo 10/9/23 Report, pg. 4.

²⁸⁵ **Exhibit 68**, Gunter Dep. 9/6/2024, at 309:5-15.

then suggests that Dr. Longo treated it as purple because that is “the color chrysotile should like.”²⁸⁶ Again, J&J wrongly presumes that all chrysotile exhibits the same refractive indices. The more important point is this though: While the center of this particle may appear “brownish gold” in this image, the refractive index measurements are taken *not* from the center of the particle but from *its edges*.²⁸⁷ Lacking that necessary qualification, J&J’s presentation of a blurry and stretched image of sample M71614-001-001 is misleading. As Dr. Longo explained, counsel for J&J had presented him with photographs of the sample which had been “increased in size or blown up quite substantially,” which caused the micrographs to appear fuzzier than how he presented them with his reports due to the loss of resolution.^{288, 289} So when Dr. Longo says he needs to look down the microscope to evaluate a particle J&J’s counsel presents him, it is not because it is always necessary to do so, but because the copies of the micrographs presented to him lack the fidelity of the originals.

²⁸⁶ Dkt. 33012-2, pg. 32.

²⁸⁷ **Exhibit 73**, Su Dep. 7/18/2024 at 11:11-17 (“Q. All I was trying to get at is that Dr. Longo evaluates the image at the border of where the fluid and the particle are coming together, at least that’s what he said, and you disagree with that as a methodology for identifying what it is that he’s looking at? A. No, I’m not disagreeing with that.”).

²⁸⁸ **Exhibit 78**, Longo 11/3/2023 Dep. at 310:1-5.

²⁸⁹ J&J’s expert, Dr. Su, admitted to photoshopping Dr. Longo’s micrographs. **Exhibit 65**, Su Dep. 7/11/2024 at 133:16-134:6.

J&J further contends that for some but not all samples, MAS used a microscope equipped with a tungsten lightbulb which emitted warmer light.²⁹⁰ As Dr. Wylie however explained, there are methods to compensate for the use of a tungsten light bulb.²⁹¹ Dr. Longo likewise testified that because “you can compensate” for the use of the tungsten lightbulb, it did not cause “any analytical problems.”²⁹² In seeming agreement, Dr. Wylie admitted that the “type of light bulb used” did not change her conclusions.²⁹³ As Dr. Longo’s findings were also consistent regardless of the type of light bulb used, this argument about the use of a tungsten light bulb is a red herring.

J&J also suggests that what Dr. Longo had found is talc (not chrysotile) because some particles exhibit red or purple edges because of a boundary effect.²⁹⁴ What J&J disregards is that its own expert, Dr. Su, has confirmed that the colors around the edge can be different without distortion.²⁹⁵ J&J’s portrayal of Dr. Longo as a careless researcher that did nothing to ascertain whether the colors at the edges of the particles were caused by distortion is baseless.

²⁹⁰ Dkt. 33012-2, pgs. 18-19.

²⁹¹ **Exhibit 71**, Wylie Dep. 6/24/2024 at 26:11-27:11.

²⁹² **Exhibit 67**, Longo 5/29/2024 Tr., 56:19-24.

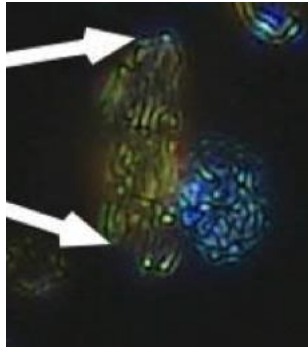
²⁹³ **Exhibit 71**, Wylie Dep. 6/24/2024 at 28:3-7.

²⁹⁴ Dkt. 33012-2, pg. 33.

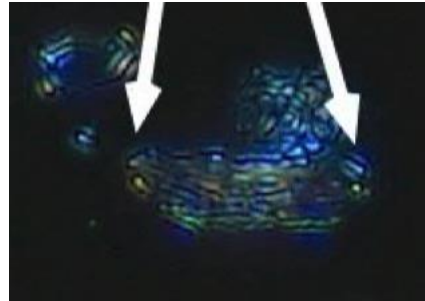
²⁹⁵ **Exhibit 65**, Su Dep. 7/11/2024 at 144:20-24.

Consistent with ISO 22262-1,²⁹⁶ Dr. Longo considered other data in distinguishing between asbestos and talc plates. As he explained, the color at the edge of the particles is not “the only thing we’re using to identify this.”²⁹⁷ He testified that “[i]f you go [to] the elongation where we have it in the 530-nanometer, you can get a better look at the structure of this as compared to everything else.”²⁹⁸ This, he explained, is significant as “talc plates don’t show up very well” in this mode.²⁹⁹

Sample M71614-001CSM-001³⁰⁰



Parallel Dispersion
RI 1.564



Perpendicular Dispersion
RI 1.561

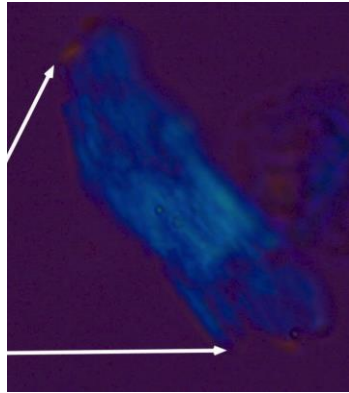
²⁹⁶ **Exhibit 41**, ISO 22262-1, § 7.2.3.6.

²⁹⁷ **Exhibit 79**, Longo 10/23/2023 Dep. at 99:22 to T100-4.

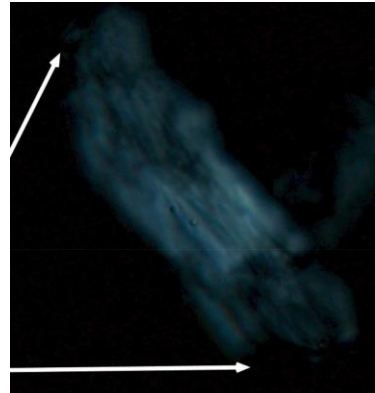
²⁹⁸ *Id.* at 100:4-7.

²⁹⁹ *Id.* at 100:7-12. In his report, Dr. Sanchez contends that a particle identified by Dr. Longo as chrysotile in sample M71614-001CSM-003 is the same color as a particle of talc. **Exhibit 80**, Sanchez Report 3/26/2024, pgs. 25-26.

³⁰⁰ **Exhibit 76**, Longo 2/28/23 Valdez M71614 Report, pgs. 32-35. Dr. Sanchez did not however consider other optical characteristics, unlike Dr. Longo, to confirm his hypothesis that what was identified was not chrysotile, but talc.



Elongation



Crossed Polars

By evaluating this sample using each of these modes, Dr. Longo could rule out the possibility that these images depict a talc plate.

Could Dr. Longo have employed other methods to differentiate between chrysotile and talc? Maybe. Was that necessary? No. As Chief Judge Wolfson recognized, whether one methodology or another is “superior,” “is an issue for cross-examination.”³⁰¹ What matters is that Dr. Longo followed ISO 22262-1, which calls for the use of central stop dispersion staining in assessing refractive indices.³⁰²

Under that protocol, Dr. Longo did not have to perform a Becke line analysis, contrary to what J&J’s expert, Dr. Su, now contends he should have. As Dr. Su admits, that is a “completely separate methodology,” and not one that is generally accepted as being required. It is, after all, not mentioned in ISO 22262-1. Nor as far as Dr. Su could identify, are there any peer reviewed publications, which suggest

³⁰¹ *J&J*, 509 F. Supp. 3d at 153 (“To the extent Defendants disagree with Dr. Longo’s methodology and advance that the Yamate protocol is superior—that is an issue for cross-examination.”)

³⁰² **Exhibit 41**, ISO 22262-1, pg. 29.

that a Becke line analysis must be performed whenever the dispersion staining method is used.^{303, 304}

Because J&J cannot dispute the reliability of the methodology Dr. Longo employed—its experts after all claim to follow ISO 22262-1—J&J’s argument that Dr. Longo calls “yellow particles purple” is no more than a disagreement over how to interpret data. As Chief Judge Wolfson recognized, “[t]hat two different experts reach opposing conclusions from the same information does not render their opinions inadmissible.”³⁰⁵ A “battle of the experts” such as this is for the factfinder to decide, not the Court.³⁰⁶

E. The use of a lab assistant goes to the weight to be given to Dr. Longo’s testimony, not its admissibility.

In labs across the country, it is common practice for principal research scientists to rely on data collected by lab assistants, analysts, and technicians. In arguing that Dr. Longo’s testimony should be excluded because he relied on assistance from Mr. Hess, J&J asks this Court to upend that system. It need not. As even J&J acknowledges,³⁰⁷ “[a]n expert witness is prepared to use assistants in

³⁰³ **Exhibit 73**, Su Dep. 7/18/2024, at 28:8-15.

³⁰⁴ In his academic writing, Dr. Su wrote that of the “three common techniques for assessing the sign and magnitude of the match/mismatch between a solid and its surrounding liquid”—Becke line, dispersion staining, and oblique illumination—“only the dispersion staining (DS) can meet the above specific needs for the routine analysis of bulk asbestos samples in commercial environmental laboratories.” **Exhibit 62**, Su (2022), at pg. 3.

³⁰⁵ *J&J*, 509 F. Supp. 3d at 190 (quoting *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 589 (7th Cir. 2000)).

³⁰⁶ *Id.* at 144 (quoting *United States v. Grace*, 455 F. Supp. 2d 1196, 199 (D. Mont. 2006)).

³⁰⁷ Dkt. 33012-2, pg. 45.

formulating his expert opinions, and normally they need not themselves testify.”³⁰⁸

“Where the expert was directly involved in the research, analysis or drafting of the report, even with substantial assistance from a colleague or associate, his involvement in and knowledge of the report are matters of weight, not admissibility.”³⁰⁹

Dr. Longo was involved in the analysis and closely supervised Mr. Hess’s work. For example, following initial test results in which Mr. Hess was comparing what he observed under the microscope with the NIST 1866b CSM, Dr. Longo directed him to look to the SG-210 chrysotile as the standard.³¹⁰ At that point, the analysis “was pretty straightforward.”³¹¹ Dr. Longo added that he agreed with Mr. Hess’s reports and that he made sure that what he reported was what they were finding.³¹² As Dr. Longo also “put together” the calculations discussed in his reports himself,³¹³ this is not a case in which the expert completely delegated the authority to an assistant to develop, conduct, document, and interpret the testing.³¹⁴ Dr.

³⁰⁸ *Dura Auto Sys. Of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 612 (7th Cir. 2002).

³⁰⁹ *Lee Valley Tools, Ltd. V. Indus. Blade Co.*, 288 F.R.D. 254, 266 (W.D.N.Y. 2013).

³¹⁰ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 152:10-154:5.

³¹¹ *Id.* at 154:3-5.

³¹² *Id.* at 157:3-21.

³¹³ **Exhibit 33**, Hess Dep. 7/10/2024, at 154:17-22.

³¹⁴ *Cf. In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1138 (S.D. Fla. 2022) (citing *Hi-Tech Pharm. Inc. v. Dynamic Sports Nutri., LLC*, No. 16-949, 2001 WL 2185699 (N.D. Ga. May 28, 2021)).

Longo's reliance on Mr. Hess's work therefore goes to the weight to be given to his testimony, not its admissibility.

F. Dr. Longo appropriately calculated birefringence consistent with EPA600/R-93/116.

J&J's final argument about Dr. Longo's PLM testing concerns his calculation of birefringence, the "quantitative expression of the maximum difference in refractive index due to double refractive."³¹⁵ Birefringence is calculated by subtracting the lowest RI value in the perpendicular orientation (the "alpha" or " (α) " value) from the highest RI value in the parallel orientation (the "gamma" (" γ ") value).³¹⁶ In other words, birefringence is the highest gamma minus the lowest alpha ($B = \max(\gamma) - \min(\alpha)$). As Dr. Longo explains, birefringence is a "key optical property" that can be used differentiate fibrous talc from chrysotile asbestos.³¹⁷ This is because chrysotile asbestos has a reported birefringence range of 0.004 to 0.017,³¹⁸ whereas fibrous talc has a birefringence several times higher, with reported ranges starting of at least 0.04 to 0.045.³¹⁹

In his reports Dr. Longo presents birefringence calculations often for individual sample assays or as a range derived from multiple sample assays. While

³¹⁵ **Exhibit 41**, ISO 22262-1, pg. 3.

³¹⁶ **Exhibit 69**, Longo MDL Dep. 5/2/2024, at 122:2-15.

³¹⁷ **Exhibit 81**, Longo 10/19/23 Report, pg. 20.

³¹⁸ **Exhibit 63**, EPA R-93 600, pg. 26.

³¹⁹ **Exhibit 65**, Su Dep. 7/11/2024, at 87:16-17; *see also id.* at 85:4-11 ("Q. The birefringence associated with talc is generally higher than this? A. Much higher."), 87:16-21 (testifying that the birefringence for talc is "about 10 times higher than the chrysotile").

J&J questions Dr. Longo's birefringence calculations, its own expert, Dr. Su, testified that he has never criticized the method by which Dr. Longo calculates birefringence.³²⁰ And considering the magnitude in the difference between the birefringence values of chrysotile and talc,³²¹ J&J's birefringence arguments fail for that independent reason. But beyond that, his method and execution are correct.

When calculating the birefringence of an individual sample, Dr. Longo subtracts the observed perpendicular value (alpha) from the parallel value (gamma). Following this approach, Dr. Longo calculated the birefringence for four samples in his November 17, 2023 report:³²²

Table 6
Chrysotile
Range of Parallel and Perpendicular RI's
RI Fluid 1.560

Chrysotile Bundle No.	CSM PLM (with HLS) Parallel RI	CSM PLM (with HLS) Perpendicular RI	BIR Calculations $\gamma - \alpha$
M71722-001			
1	1.564	1.560	0.004
2	1.568	1.560	0.008
3	1.566	1.562	0.004
4	1.566	1.561	0.005
	Avg. 1.566	Avg. 1.561	Avg. 0.005
M71722-002			
1	1.564	1.560	0.004

As the birefringence values range from 0.004 to 0.008, they all fall within the scientifically accepted range of chrysotile (0.004 to 0.017).

³²⁰ **Exhibit 73**, Su Dep. 7/18/2024, at 116:11-18.

³²¹ **Exhibit 65**, Su Dep. 7/11/2024, at 87:16-21 (testifying that the birefringence for talc is "about 10 times higher than the chrysotile").

³²² **Exhibit 28**, Longo Third Supplemental MDL Report 11/17/23, pg. 20.

Dr. Longo also reports birefringence values based on ranges of refractive indices. He does this by subtracting the high and low alpha values from the high and low gamma values, respectively. In criticizing this approach, J&J overlooks that the EPA has similarly calculated the range for birefringence from indices of refraction.³²³

Mineral	Morphology and Color ¹	Refractive Indices ¹ or γ^1	Birefringence ¹
Chrysotile (asbestiform serpentine)	Many forms. Fiber bundles have splined ends and 'frinks'. Aspect ratio typically >10:1. Colorless ¹	1.493-1.546 1.517-1.567 1.533-1.549 1.549-1.558 1.529-1.559 1.537-1.567 1.544-1.553 1.552-1.561	0.004-0.017

J&J's expert, Dr. Su, validates Dr. Longo's presentation of birefringence. In his testimony he has explained that "when you have ranges like this, you would calculate the range of birefringence in this case like what we see on the page here, by taking the maximum high end ... of gamma, subtracted by the high end of alpha, and the low end of gamma subtracted by the low end of alpha as they did in this example[.]"³²⁴ Thus, contrary to the position J&J takes now, Dr. Su's testimony confirms the acceptability of calculating a range for birefringence based on the range of the alpha and gamma RI values as Dr. Longo did.

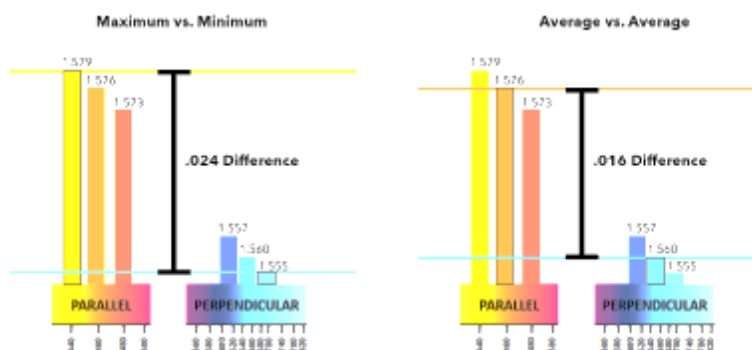
Aside from taking a position at odds with one of its own experts, J&J's mischaracterization of Dr. Longo's calculations runs deeper. J&J claims that by averaging the refractive index values, Dr. Longo decreases the birefringence values,

³²³ **Exhibit 63**, EPA R-93 600, pg. 26.

³²⁴ **Exhibit 65**, Su Dep. 7/11/2024, at 86:10-23.

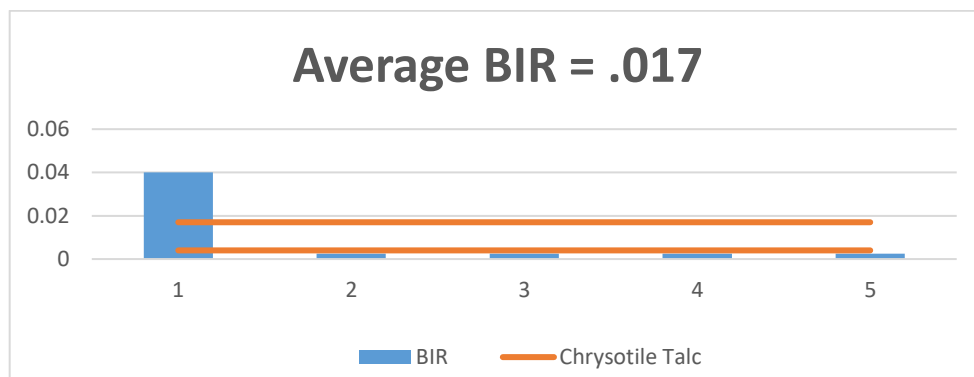
making the particles appear more like asbestos than talc. As an elementary statistical proposition, however, if you have three sample observations and calculate birefringence based on the averages of each's gamma and alpha values, rather than the maximum and minimum, the delta between the averaged values may be less than the maximum and minimum ones. But as a practical matter, one cannot make talc appear more like asbestos by simply averaging the refractive index values.

Consider J&J's illustration on page 57 of its brief:



As a mathematical exercise, J&J is correct: the difference between the maximum and minimum values is greater than the difference between averaged ones. But J&J fails to appreciate that the difference between the maximum RI (1.579) and minimum RI (1.555) values in the illustration above is just .024, which means that while the particle at issue in their hypothetical is not chrysotile, it is also not talc.

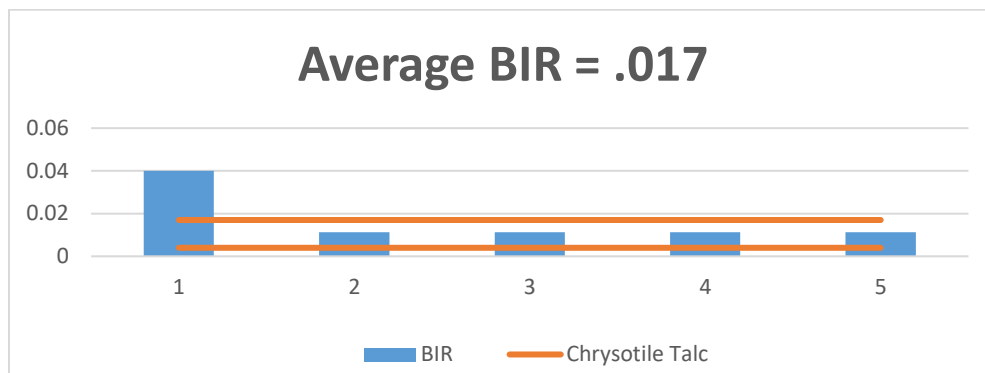
Recall that J&J’s expert Dr. Su has explained that the birefringence for talc is “10 times higher” than that of chrysotile and that it is at least 0.04.³²⁵ For a sample to have a birefringence greater than 4, which is necessary for the particle to be classified as talc, the other sampled values must have birefringence values approaching zero, if not zero. To illustrate, if there are 5 samples and the average birefringence of the samples is .010 (which reflects the midway point in the birefringence range for chrysotile), and one of the samples has a birefringence rate of 0.04 (the low end for talc), the other four samples would have to have birefringence values of 0.00125.



As this illustration shows, for the birefringence value of one sample to fall within the range of talc, the other samples would have birefringence values well below that of chrysotile.

³²⁵ **Exhibit 65**, Su Dep. 7/11/2024, at 87:16-21 (testifying that the birefringence for talc is “about 10 times higher than the chrysotile”).

If you were to increase the average of the 5 samples to 0.017 (the high end for chrysotile), the other four samples would have an average of 0.010.

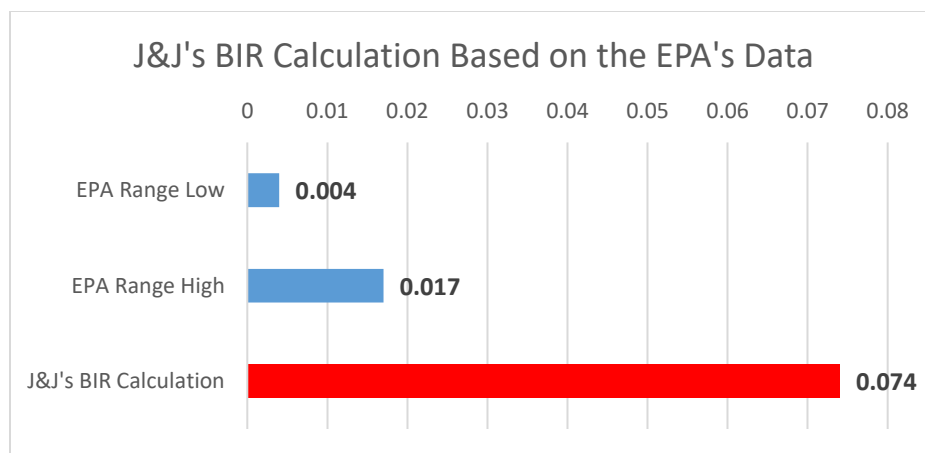


In that case, four of the samples would fall squarely within the range of chrysotile (0.004 to 0.017). As birefringence is an “individual value” for each sample,³²⁶ four samples would qualify as chrysotile even in this scenario. If anything then, J&J’s argument adds support to Dr. Longo’s identification of chrysotile.

This is not just a theoretical problem. Were one to calculate birefringence from the EPA’s numbers using only the highest gamma (1.567) and lowest alpha (1.493),³²⁷ as J&J suggests, the resulting birefringence value would be 0.074, which falls far outside the range reported by the EPA of 0.004 to 0.017.

³²⁶ Exhibit 65, Su Dep. 7/11/2024, at 86:1-8.

³²⁷ Exhibit 63, EPA R-93 600, pg. 26.



Because J&J's approach deviates from the EPA's numbers so significantly, it is not Dr. Longo that has failed to follow an accepted methodology, but J&J.

III. Based on the conclusions of regulatory and health agencies and scientific and medical literature, Plaintiffs' causation experts concluded that asbestos could cause ovarian cancer.

Plaintiffs' general causation experts hold to the same opinion—that Defendants' talcum powder products can cause ovarian cancer.³²⁸ That opinion is supported by the significant and consistent evidence that Defendants' talcum powder products have contained asbestos in numerous forms—chrysotile, tremolite, anthophyllite, and actinolite—since the 1950s.

The International Agency for the Research on Cancer (IARC) has been evaluating the cancer-causing potential of asbestos since the 1970s.³²⁹ It is well-

³²⁸ For a summary of the opinions of Plaintiffs' general causation experts, please see The Plaintiffs' Steering Committee's Response to the Court's April 30, 2024 Memorandum and Order Regarding Judge Wolfson's *Daubert* Opinion on General Causation, ECF 33009 (July 23, 2024).

³²⁹ IARC (2012) Monograph 100C Asbestos (2012), attached as **Exhibit 82** ("Asbestos was considered by previous IARC Working Groups in 1972, 1976, and 1987. . . .") (citing IARC (1977). Some miscellaneous pharmaceutical substances. IARC Monogr Eval Carcinog Risk Chem Man, 13: 1–255).

accepted that asbestos is a known human carcinogen. In its Monograph 100C, the IARC Working Group reviewed relevant evidence and concluded that exposure to asbestos of six fiber types (chrysotile, actinolite, amosite, anthophyllite, crocidolite, and tremolite) and talc containing asbestiform fibers is a cause of ovarian cancer.³³⁰

Defendants argue that IARC's findings and certain scientific publications do not apply to the facts of this case because: 1) the studies relied upon involved heavy occupational exposure; 2) the studies were confounded by patients being misdiagnosed with ovarian cancer instead of primary peritoneal mesothelioma; and 3) the studies finding an association "generally involve exposure to crocidolite – regarded as the most potent of the various asbestos types"³³¹ which has not been identified in Defendant's talcum powder products. Each of these arguments fail.

A. The conclusion by regulatory and health agencies that exposure to asbestos can cause ovarian cancer is not limited to occupational exposure.

1. IARC does not limit its conclusion that exposure to asbestos can cause ovarian cancer to "occupational exposure."

IARC's 2012 Monograph 100C makes clear that its conclusions regarding asbestos and ovarian cancer are not limited to those individuals who are exposed in an occupational setting. The Monograph begins:

³³⁰ *Id.* at 219, 294 ("There is *sufficient evidence* in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary.")

³³¹ Defendants' Mot., ECF Dkt. 33012-2, at 87.

The conclusions reached in this *Monograph* about asbestos and its carcinogenic risks apply to these six types of fibers *wherever they are found*, and that includes talc containing asbestiform fibers.³³²

In reaching its decision, IARC considered all published occupational exposure studies *and* non-occupational, environmental studies. The Monograph states that:

The Working Group noted that a *causal association* between exposure to asbestos and cancer of the ovary was *clearly established*, based on five strongly positive cohort mortality studies of women with heavy occupational exposure to asbestos (Acheson *et al.*, 1982; Wignall & Fox, 1982; Germani *et al.*, 1999; Berry *et al.*, 2000; Magnani *et al.*, 2008). The *conclusion received additional support* from studies showing that women and girls with *environmental, but not occupational exposure to asbestos* (Ferrante *et al.*, 2007; Reid *et al.*, 2008, 2009) had positive, though non-significant, increases in both ovarian cancer incidence and mortality.³³³

And the Monograph ends with a final “Evaluation” which contains no limitation on the applicability of the Monograph’s conclusion:

There is *sufficient evidence* in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary.³³⁴

Nothing in the Monograph suggests that the IARC classification of asbestos as an ovarian cancer carcinogen is limited to occupational exposure. Rather, the Working Group explicitly states “that a *causal association* between exposure to asbestos and

³³² **Exhibit 82**, IARC (2012) Monograph 100C Asbestos (2012), at 219.

³³³ *Id.* at 256 (emphasis added).

³³⁴ *Id.* at 293.

cancer of the ovary was *clearly established*” based on both occupational and environmental studies.³³⁵

Moreover, the IARC 2012 Working Group considered the genital application of talcum powder as a primary route of asbestos exposure for the general population, stating: “Consumer products (e.g., cosmetics, pharmaceuticals) are the primary source of exposure to talc for the general population. Inhalation and dermal contact (i.e., through perineal application of talcum powders) are the primary routes of exposure.”³³⁶ In the same section, the Working Group describes studies finding that talc contains detectable levels of chrysotile, tremolite, and anthophyllite (the same types of asbestos identified by Drs. Longo & Rigler).³³⁷ Had the Working Group intended to limit the application of asbestos as a Group 1 human carcinogen to only “heavy occupational” exposure and not exposure to asbestos through the genital use of cosmetic talcum powder, they could have clearly done so. They did not.

Further, in IARC’s 2024 reclassification of talc (both lamellar and fibrous) as a probable carcinogen (Group 2A), the Working Group affirmed the conclusion that asbestos’s classification as a Group 1 carcinogen was intended to apply to cosmetic talcum powder containing asbestos:

³³⁵ *Id.*

³³⁶ *Id.* at 232.

³³⁷ *Id.* (citing Rohl, *et al.*, 1976; Blount, 1991; and Van Gosen, 2006, all of which are cited by Drs. Longo, Rigler, Cook and Krekeler).

Talc containing asbestos is currently classified as *carcinogenic to humans* (Group 1), as part of the classification of asbestos carried out in *IARC Monographs Volume 100C*. There is *sufficient* evidence that asbestos causes mesothelioma and cancers of the lung, larynx, and ovary in humans. . . .

Talc containing asbestos remains part of the definition of asbestos (classified in Group 1) and was not evaluated for this volume.

The Working Group concluded that contamination of talc with asbestos remains a major concern and may lead to exposure of workers and the general population . . . The Working Group also noted that contamination of talc products with asbestos has been documented and that industry standards used to assess talc in cosmetic and pharmaceutical products have often not been sufficiently sensitive to rule out contamination with asbestos.³³⁸

In sum, Defendants' assertion that IARC's conclusion regarding asbestos and ovarian cancer was based solely on occupational studies and therefore, not applicable to the genital application of talcum powder is refuted by the clear text of IARC's statements in 2012, and most recently, in July 2024. Plaintiffs' experts properly rely on both IARC statements in opining that exposure to asbestos can cause ovarian cancer.

2. The Food and Drug Administration, National Cancer Institute, Environmental Protection Agency, and other governmental agencies do not limit their conclusions that exposure to asbestos can cause ovarian cancer to occupational exposure.

³³⁸ IARC, IARC Monographs evaluate the carcinogenicity of talc and acrylonitrile, IARC Monographs Volume 136, Questions & Answers (Q&A), at 5 (July 5, 2024) (citations omitted) (emphasis added), attached as **Exhibit 83**.

Other health and regulatory agencies have considered the question of whether exposure to asbestos can cause ovarian cancer and have concluded that it does, irrespective of whether the exposure was occupational or environmental. Plaintiffs' experts rely on the statements of these authoritative bodies as well in support of their opinion that exposure to asbestos through talcum powder can cause ovarian cancer.

The National Cancer Institute has found that exposure to asbestos can cause ovarian cancer without limiting its finding to those individuals who were exposed in an occupational setting.³³⁹ The EPA has likewise concluded that asbestos can cause ovarian cancer, making no distinction whether the exposure was in an occupational setting or from an environmental exposure such as cosmetic talc.³⁴⁰

In addition, and importantly, the IWGACP explicitly focuses on exposure to asbestos from cosmetic talc.^{341, 342} Following a public hearing in February 2020 and the receipt of numerous written submissions by all interested parties, the IWGACP published a White Paper with voluminous appendices in December 2021 in which it

³³⁹ National Cancer Institute, <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/asbestos>, last accessed August 18, 2024.

³⁴⁰ Environmental Protection Agency, Fed. Reg. Vol. 89, No. 61 (March 28, 2024), Rules and Regulations, attached as **Exhibit 84**.

³⁴¹ **Exhibit 1**, White Paper at 4, n.1.

³⁴² The IWGACP includes representatives from eight federal agencies: Food and Drug Administration (FDA), National Institutes for Occupational Safety and Health (NIOSH), National Institute of Health (NIH)/National Institute of Environmental Health Sciences (NIEHS), Occupational Safety and Health Administration (OSHA), Environmental Protection Agency (EPA), Consumer Product Safety Commission (CPSC), the National Institute of Standards & Technology (NIST), and the USGS, each of which has expertise in asbestos-testing and/or asbestos-related issues (e.g., from a health perspective), or because they regulate some of the consumer products that contain talc as an ingredient. *Id.* at 7, n.7.

concluded that: “Exposure to asbestos may also lead to diseases, . . . including cancers of the . . . ovaries.”³⁴³ The entire premise of the IWGACP’s work was exposure to asbestos through the use of cosmetic talc.

Defendants’ assertions that only asbestos exposure in occupational settings can cause ovarian cancer are inconsistent with the evidence. Plaintiffs’ experts’ reliance on the statements of these regulatory and governmental agencies in formulating their causation opinions is appropriate and reliable.

3. The bellwether plaintiffs were exposed to asbestos on a daily basis for decades as a result of their use of Johnson’s Baby Powder and Shower to Shower.

Defendants argue that even if asbestos causes ovarian cancer, perineal talc use is not remotely comparable to occupational exposure and cite as support the weight percentages of asbestos found by Drs. Longo and Rigler in individual analyses of Defendants’ talcum powder.³⁴⁴ Defendants point to a range of percentages of asbestos by weight reported by Drs. Longo and Rigler – 0.0092% to 0.0000033% – and suggest that the amount of exposure is negligible. This is simply not the case.

First, regulatory agencies and J&J agree that there is no known safe level of asbestos. According to OSHA, “There is no ‘safe’ level of asbestos exposure for any type of asbestos fiber.”³⁴⁵ NIOSH has similarly stated that, “Evaluation of all

³⁴³ **Exhibit 1**, White Paper, at 9.

³⁴⁴ Defs.’ Mot., ECF Dkt. 33012-2, at 89-91.

³⁴⁵ OSHA, Asbestos, <https://www.osha.gov/asbestos>, last accessed August 19, 2024.

available human data provides no evidence for a threshold or for a ‘safe’ level of asbestos exposure.”³⁴⁶ J&J’s corporate representatives have testified that there is no known safe level of asbestos exposure.³⁴⁷ Defendants’ suggestion that “9.2 thousands of percent” exposure is irrelevant from a health perspective is misleading and mischaracterizes the testimony of their own corporate representative witness.

Second, the individual weight percent calculations of the amount of asbestos in a single sample represents *millions* fibers of asbestos per container. For the samples in which Drs. Longo and Rigler identified amphibole asbestos, the volume of asbestos fibers per container ranges from approximately 665,000 to 126,000,000.³⁴⁸ These exposures *per bottle* represent significant amounts of exposure to asbestos fibers on a daily basis.

Third, the bellwether plaintiffs used and applied Johnson’s Baby Powder and/or Shower to Shower to their genital area *daily* for decades—the shortest period being 20 years, the longest being 55 years, and the average time period being just

³⁴⁶ “WORKPLACE EXPOSURE TO ASBESTOS Review and Recommendations,” DHHS (NIOSH) Publication No. 81-103, (November 1980), attached as **Exhibit 85**.

³⁴⁷ Trial Testimony of Dr. John Hopkins in *Barden v. Brenntag North America, et. al*, MID-L-0932-17AS, July 22, 2019, at p. 48-49 (Q “Johnson & Johnson knows there is no safe level of asbestos exposure, correct? A. Scientists have not shown a safe level. So, yeah, I would not disagree.), attached as **Exhibit 86**.

³⁴⁸ See Amphibole Asbestos Found in Historical Johnson’s Baby Powder and Shower to Shower 1960s to 2000s (chart of fibers per gram, ounce, etc.), attached as **Exhibit 87**.

over 42 years.³⁴⁹ Over the course of these decades, bellwether plaintiffs used between 221 and 568 containers of Johnson's Baby Powder and Shower to Shower.³⁵⁰ For each plaintiff, the majority of the usage was during the time period when J&J sourced talc from Vermont. Drs. Longo and Rigler found that more than 75% of samples manufactured during that period contained asbestos.³⁵¹ For the time period after 2003 when talc was sourced from China, Drs. Longo and Rigler identified asbestos in more than 80% of the samples.³⁵²

In sum, the bellwether plaintiffs were directly exposed to asbestos by applying talcum powder to their genital areas on a near daily, if not daily basis, for *decades*. Plaintiffs' experts properly based their causation opinions on the facts of the individual plaintiffs' genital use of talcum powder, Drs. Longo and Rigler's results regarding the amount of asbestos identified during the relevant years, and the conclusions of authoritative bodies such as IARC, NIOSH, OSHA, as well as the scientific literature.

B. IARC considered and rejected the possibility that misdiagnosis of ovarian cancer confounded the results of relevant studies.

³⁴⁹ See William E. Longo, Jr. Expert Report, MDL Johnson's Baby Powder Application and Exposure Container Calculations for Six Ovarian Cancer Victims Bellwether Cases, attached as **Exhibit 88**.

³⁵⁰ *Id.*

³⁵¹ *Id.*

³⁵² *Id.*

Defendants argue that the epidemiologic literature does not support a link between exposure to asbestos and ovarian cancer suggesting the literature was confounded because “until very recently peritoneal mesothelioma was often misdiagnosed as ovarian cancer.”³⁵³ This is nothing more than wishful thinking on their part.

First, IARC carefully considered the possibility of misdiagnosis and determined that there was no evidence suggesting that such confounding had occurred to such a degree it would make a difference:

The Working Group carefully considered the possibility that cases of peritoneal mesothelioma may have been misdiagnosed as ovarian cancer, and that these contributed to observed excesses. *Contravening that possibility is the finding that three of the studies cited here specifically examined the possibility that there were misdiagnosed cases of peritoneal mesothelioma, and all failed to find sufficient numbers of misclassified cases.* The Working Group noted that the possibility of diagnostic misclassification had probably diminished in recent years because of the development of new immunohistochemical diagnostic techniques.³⁵⁴

Second, Plaintiffs’ experts not only rely on IARC’s finding, but also studies published since 2012, all of which demonstrate a statistically significant increased risk with pathologically confirmed cases of ovarian cancer. In 2011, Camargo, *et al.* published a meta-analysis of all asbestos-ovarian cancer studies.³⁵⁵ Camargo

³⁵³ Defendants’ Mot., ECF Dkt. 33012-2, at 88.

³⁵⁴ IARC Monograph 100C, **Exhibit 82**, at 256 (emphasis added).

³⁵⁵ M. Constanza Camargo, et al., *Occupational Exposure to Asbestos and Ovarian Cancer: A Meta-Analysis*, Environ. Health Perspectives 119, no. 9 (Sep. 2011), at 1211–17, attached as **Exhibit 89**.

reported that the effect estimates were similar for studies with and without pathologic confirmation.

In 2021, Nowak, *et al.*, conducted a systematic review and meta-analysis of both cohort studies – 10 occupational and 3 environmental studies, plus one case control study.³⁵⁶ The meta-analysis of all studies resulted in an overall SMR of 1.88 (95% CI 1.47-2.39). Importantly, Nowak and colleagues considered the possibility of misdiagnosis and did an analysis of studies with and without histological verification. The authors found differences in the pooled effect estimates (1.89 v. 1.98) to be negligible, suggesting there is no issue of concern.

In 2023, Kim, *et al.* published an up-to-date meta-analysis of both occupational and environmental studies examining the relationship between asbestos exposure and ovarian cancer.³⁵⁷ The study found a SMR of 1.72 (95% CI: 1.43-2.06; p=0.0349; 15 studies), noting that the “possibility of misdiagnosis in earlier studies cannot be completely ruled out, recent findings suggest a robust correlation between asbestos exposure and ovarian cancer.” Lastly, in 2023, Turati, *et al.* “conducted a systematic review and meta-analysis, based on the most updated evidence” and found that “misclassification alone cannot explain the observed

³⁵⁶ Nowak, et al., *Asbestos Exposure and Ovarian Cancer – a Gynaecological Occupational Disease. Background, Mandatory Notification, Practical Approach*. Geburtsh Frauenheilk 2021; 81: 555–561, attached as **Exhibit 90**.

³⁵⁷ Kim SY et al., *Asbestos Exposure and Ovarian Cancer: A Meta-analysis, Safety and Health at Work*, <https://doi.org/10.1016/j.shaw.2023.11.002>, attached as **Exhibit 91**.

excesses of both mesothelioma and ovarian cancer.”³⁵⁸ None found that misdiagnoses could explain the increased risk demonstrated across all studies.

Defendants’ argument mischaracterizes the findings of the epidemiologic literature. Plaintiffs’ experts have properly considered and relied on not only IARC’s classification but the findings from epidemiologic studies published since IARC’s consideration of the question. Any debate regarding the misdiagnosis of ovarian cancer and the effect on the outcome of epidemiologic studies is properly left for cross-examination and is not a proper basis to exclude the testimony.

C. IARC’s classification of asbestos as a cause of ovarian cancer applies to ALL types of asbestos.

Defendants also argue that Plaintiffs’ experts’ opinions are unreliable because epidemiological studies involve exposure to “crocidolite asbestos, which is not alleged to be a contaminant of talc.”³⁵⁹ Nothing could be further from the truth.

Plaintiffs’ experts consider and rely on numerous authoritative sources and epidemiologic studies to reach their opinion that exposure to asbestos (all types) can cause ovarian cancer. First, IARC is quite clear that its 2012 classification applies to all types of asbestos: “All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) are *carcinogenic to humans (Group 1)*.”³⁶⁰

³⁵⁸ Turati F., et al. *Occupational Asbestos Exposure and Ovarian Cancer: Updated Systematic Review*. *Occup Med (Lond)*. 2023 Dec 30;73(9):532-540, attached as **Exhibit 92**.

³⁵⁹ Defs.’ Mot., ECF Dkt. 33012-2, at 91-92.

³⁶⁰ IARC Monograph 100C, **Exhibit 82**, at 293.

Second, the National Cancer Institute has found that exposure to asbestos (without delineating a specific fiber type) can cause ovarian cancer.³⁶¹ Third, the EPA defines asbestos to include all six fiber types and has concluded that asbestos can cause ovarian cancer.³⁶² The IWGACP when stating, “[e]xposure to asbestos may also lead to diseases, . . . including cancers of the . . . ovaries”³⁶³ makes no distinction between the exposures to different types of asbestos.

Defendants cite no epidemiological studies that support their argument. All meta-analysis – those cited by Defendants and those cited above – Camargo (2011), Nowak (2021), Kim (2023), and Turati (2023) – reach conclusions about asbestos exposure and ovarian cancer, not limiting the applicability of their findings to crocidolite asbestos alone.

In sum, the evidence from Defendants’ own documents, the geologic peer-reviewed literature, and Drs. Longo and Rigler’s testing provide consistent and clear evidence that Johnson’s Baby Powder and Shower to Shower contain asbestos and have for more than **50 years**. The overwhelming weight of the evidence – i.e., classifications by regulatory and health related authoritative bodies and epidemiologic studies – support the conclusion that exposure to asbestos can cause

³⁶¹ National Cancer Institute, <https://www.cancer.gov/about-cancer/causes-prevention/risk/substances/asbestos>, last accessed August 18, 2024.

³⁶² Environmental Protection Agency, Fed. Reg. Vol. 89, No. 61 (March 28, 2024), Rules and Regulations, **Exhibit 84**.

³⁶³ **Exhibit 1**, White Paper at 9.

ovarian cancer. Plaintiffs' causation experts properly rely on this evidence in support of their opinion that talcum powder can cause ovarian cancer.

IV. Reliable scientific evidence establishes asbestos was present in the talc used to source Defendants' talcum powder products.

Despite substantial evidence, Defendants argue that the PSC lacks credible scientific proof of asbestos presence in the talc ore used to source their products. They first assert that "Drs. Cook and Krekeler unreliably base their opinions on counsel-generated collections and summaries of documents."³⁶⁴ This assertion is directly contravened by Drs. Cook's and Krekeler's testimonies and reports. Defendants next contend that the "documents on which Drs. Cook and Krekeler rely in any event fail to furnish a reliable basis for their conclusions," highlighting a few inadvertently included examples not sourced from the correct mines or intended for industrial use.³⁶⁵ This contention is also meritless. Defendants fail to discredit or even acknowledge the numerous examples of Defendants' data that Drs. Cook and Krekeler reference, all showing positive test results for asbestos or fibrous talc.

A. The methodology and evidence relied upon by Drs. Cook and Krekeler are proper.

Defendants attempt to undermine Drs. Cook and Krekeler's methodology and document sources fails. Both experts comprehensively detail their methodology and data throughout their reports and deposition testimony. Drs. Cook and Krekeler each

³⁶⁴ Defs.' Mot. at 94, ECF No. 33012-2.

³⁶⁵ *Id.* at 95.

reviewed hundreds of documents, conducting independent research, literature searches, and examining corporate documents and deposition testimony.

Dr. Krekeler, for instance, evaluated x-ray diffraction data, core data, electron microscopy data, bulk chemistry data, ore and mineral descriptions, and other relevant information.³⁶⁶ He conducted extensive literature reviews, including peer-reviewed sources, and referenced publications on the geology of Vermont, Italy, and China, along with other materials that geologists commonly rely on, such as the United States Geological Survey from the Bureau of Mines.³⁶⁷ These methods and materials are widely accepted in the field of geology and are standard in consultancy practices.³⁶⁸ He also reviewed corporate documents and deposition testimony.³⁶⁹ Dr. Krekeler relied on his academic and private sector experience in forming his opinions.³⁷⁰ Similarly, Dr. Cook conducted thorough research and document reviews in compiling his report. He examined published literature and corporate documents provided in the litigation, adhering to standard research methodologies with the same

³⁶⁶ See January 25, 2019, Deposition of Mark Krekeler, Ph.D. (“Krekeler Dep.”) at 324:2–11, attached as **Exhibit 93**.

³⁶⁷ *Id.* at 324:12–325:14; Krekeler Report at 2, attached as **Exhibit 94**.

³⁶⁸ **Exhibit 93**, Krekeler Dep. at 324:9–11, 325:2–5.

³⁶⁹ **Exhibit 94**, Krekeler Report at 2.

³⁷⁰ *Id.*

rigor he applied as a professor of geology and practices as a consultant for mining companies.³⁷¹

Defendants claim, based on charts of company documents contained in Drs. Cook's and Krekeler's reports, that the experts inappropriately relied on documents selected and summarized by Plaintiffs' counsel in reaching their conclusions.³⁷² First, the only documents supplied by counsel were requested by the experts. Since all corporate documents are in the custody of Plaintiffs' counsel, Drs. Cook and Krekeler could not independently obtain them and, therefore, requested and reviewed those they would typically rely on as geologists.³⁷³ An expert's choice of scientific publications or relevant materials for review impacts the weight and credibility of their opinions, not the admissibility of their testimony.³⁷⁴ Even when an expert seemingly "ignores" studies or information supporting an opposing view, "it is not the province of the court to choose between the competing theories when both are supported by reliable scientific evidence."³⁷⁵

³⁷¹ See January 30, 2019, Deposition of Robert Cook, Ph.D. ("Cook Dep.") at 456:1–458:5, 460:19–462:16, attached as **Exhibit 95**. See also Cook Report at 3, attached as **Exhibit 96**; **Exhibit 96**, Cook Report Ex. B at 3.

³⁷² These charts include test results positive for asbestos and test results positive for fibrous talc.

³⁷³ See **Exhibit 93**, Krekeler Dep. at 325:15–326:16.

³⁷⁴ *In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 2017 WL 6397721, at *7 (D. Minn. Dec. 13, 2017). Defendants are free to challenge Drs. Cook and Krekeler on cross-examination or present their own experts to attack Drs. Cook's and Krekeler's scope of review. *Id.*

³⁷⁵ *Kuhn v. Wyeth, Inc.*, 686 F.3d 618, 633 (8th Cir. 2012); see also *In re NuvaRing Prods. Liab. Litig.*, 2013 WL 791787, at *2-3 (E.D. Mo. Mar. 4, 2013).

Next, Defendants ignore both experts' testimonies. Dr. Cook clarified that the chart is composed of documents he reviewed and summarized in narrative form and that after digesting the Hopkins chart, he suggested presenting the results in a chart for clarity.³⁷⁶ Likewise, Dr. Krekeler explained that he reviewed documents and selected certain ones for Plaintiffs' counsel to compile into a chart.³⁷⁷ While Plaintiffs' attorneys performed the clerical task of creating the chart, both experts verified the charts and confirmed that the documents were documents they considered in reaching their opinions. Drs. Cook and Krekeler requested the creation of the charts based on their examinations of the underlying documents, reviewed the charts, and contributed to their entries.

Based on these charts, Defendants maintain that Drs. Cook and Krekeler may not act "as a mere vessel" for information from Plaintiffs' counsel, citing *State Farm Fire & Casualty Company v. Electrolux Home Products, Inc.*³⁷⁸ Reliance on this case is misplaced. There, an expert was excluded for improperly analyzing data from two disparate sources "rather than two comparable sources."³⁷⁹ While the information had come from counsel, it was not excluded for that reason. Rather, the court noted the expert's failure to ensure that her analysis was based on comparable

³⁷⁶ **Exhibit 95**, Cook Dep. at 55:19–57:10, 57:18–24, 58:10–59:2, 60:3–8.

³⁷⁷ **Exhibit 93**, Krekeler Dep. at 40:6–41:14.

³⁷⁸ Defs.' Mot. at 94, ECF No. 33012-2 (citing *State Farm Fire & Cas. Co. v. Electrolux Home Prods., Inc.*, 980 F. Supp. 2d 1031, 1048 (N.D. Ind. 2013)).

³⁷⁹ *Id.* at 1038.

data.³⁸⁰ Here, no statistical comparison is involved; the charts were simply clerical compilations of documents reviewed by Drs. Cook and Krekeler.

Defendants further contend that Drs. Cook and Krekeler relied on counsel's summaries of the evidence, citing *Crowley v. Chait*.³⁸¹ Not so. And *Crowley* is inapplicable. There, the expert relied only on a summary of 8 depositions out of 150 that were available and minimal independent research. Because the expert's conclusions were based on a filtered version of events, instead of information gleaned from his own investigation and analysis, they were unreliable. In contrast, Drs. Cook and Krekeler reviewed extensive literature and geological analyses, reports, maps, core logs, and test results, and produced their own comprehensive reports.³⁸² Their conclusions are based on documents that the experts examined and included on their reliance lists. The charts compiled by counsel merely facilitate the Court's understanding of the data reviewed by the experts.³⁸³

B. The materials relied upon by Drs. Cook and Krekeler support their reports and conclusions.

³⁸⁰ *Id.* at 1039.

³⁸¹ Defs.' Mot. at 94 (citing *Crowley v. Chait*, 322 F. Supp. 2d 530, 546 (D.N.J. 2004)).

³⁸² See, e.g., **Exhibit 96**, Cook Report, Exhibit B (Dr. Cook's extensive list of materials and data considered, including 44 pieces of published literature, 7 deposition transcripts and accompanying exhibits, 791 internal documents of Defendants, 49 other relevant documents, and the expert report of Dr. Krekeler); **Exhibit 94**, Krekeler Report, Exhibit B (Dr. Krekeler's extensive list of materials and data considered, including 172 pieces of published literature, more than 297 internal documents of Defendants, 10 deposition transcripts, 289 deposition exhibits, and 4 expert reports).

³⁸³ See **Exhibit 93**, Krekeler Dep. at 40:6–41:14; **Exhibit 95**, Cook Dep. at 55:19–57:10.

Defendants misleadingly select a few sources, disregarding the comprehensive body of evidence that Drs. Cook and Krekeler rely on, to argue that the experts' opinions are not supported by the data upon which they rely. Yet, Drs. Krekeler and Cook reviewed and referenced numerous documents regarding talc mines and the testing of ore and finished products that support their opinions.³⁸⁴ The presence of a few documents and reports allegedly involving other mines does not invalidate the substantial data from the mines the parties agree were used to source talc. Rather, the purpose of those similar examples was to provide useful, foundational information. Defendants' perceived flaws in Drs. Cook's and Krekeler's reports are matters for cross-examination, not bases for excluding their reports.³⁸⁵

In seeking to exclude many valid observations based on a few examples, Defendants misrepresent the experts' testimonies. For instance, they claim that Dr. Cook cites studies and literature not specific to the mines used for cosmetic talc products, overlooking that Dr. Cook considered these materials because of their relevance to the particular regions' geology.³⁸⁶ Dr. Cook references a letter from Bill

³⁸⁴ **Exhibit 93**, Krekeler Dep. at 324:2–325:15; **Exhibit 95**, Cook Dep. 456:1–458:5.

³⁸⁵ *See Violas v. GMC*, 73 F. Supp 2d 452, 462 (D.N.J. 1999) (quoting *Walker v. Yellow Freight Sys., Inc.*, 1999 U.S. Dist. LEXIS 15012, No. CIV.A.98-3565, 1999 WL 757022, at *8 (E.D. La. Sep. 24, 1999)) (explaining that “‘the perceived flaws’ in an expert’s testimony often should be treated as ‘matters properly to be tested in the crucible of the adversarial system, ‘not as ‘the basis for truncating that process.’”).

³⁸⁶ Defs.’ Mot. at 95 n.240.

Ashton to the Colorado School of Mines regarding the Val Chisone Valley in Italy, which includes the Fontane Mine where Defendants' talc was mined.³⁸⁷ He cites the letter to document the valley's mineralization, providing a geological context that does not exclude the mine's location from its analysis.³⁸⁸ Dr. Cook notes that he used the documents regarding the Val Chisone Valley as "general geologic information so that there was a foundation upon which the more detailed information could be anchored."³⁸⁹ Notably, Defendants do not challenge the numerous other references that Dr. Cook cites related to the Italian talc used for their products, including Dr. Pooley's report from the University of Cardiff and multiple corporate documents.³⁹⁰

Defendants similarly mischaracterize Dr. Cook's descriptions of the Vermont mines. They cite Dr. Cook's report to claim that various mines were not used for their products. However, Dr. Cook used these mines to set "the geological framework within which the ultramafic rocks occurred."³⁹¹ His report clarifies that "the talc deposits described in these publications occur as part of the same geological belt as the mines that sourced J&J's Talcum Powder Products."³⁹² He does not assert that Defendants' products were sourced from those mines. Dr. Krekeler's report

³⁸⁷ See **Exhibit 97**, Cook Dep. Ex. 20, Methodology X-Ray limitations; 8/6/71 letter to W. T. Caneer from W. Ashton.

³⁸⁸ **Exhibit 95**, Cook Dep. at 246:22–249:23.

³⁸⁹ *Id.* at 458:14–459:3.

³⁹⁰ See **Exhibit 96**, Cook Report at 10 (outlining the minerology in Italy and numerous corporate documents that discuss the asbestos and fibrous talc found in Italian talc).

³⁹¹ **Exhibit 95**, Cook Dep. at 458:15–21.

³⁹² **Exhibit 96**, Cook Report at 11.

similarly discusses the Geological Survey's information on Vermont mines and the Appalachian Ultramafic Belt, providing a regional geological context that includes the talc mines.³⁹³ Both experts gave background information, discussed regional geology and its application, and then focused on specific mines using Defendants' internal documents consisting of core logs, individual sample tests, maps,³⁹⁴ and mine-specific analyses.³⁹⁵ Indeed, evidence from separate talc deposits is relevant due to their geological relation.³⁹⁶

³⁹³ **Exhibit 94**, Krekeler Report at 10; **Exhibit 93**, Krekeler Dep. at 315:10–316:6.

³⁹⁴ Examples include IMERYYS 441340 at 441346, attached as **Exhibit 98** (maps of Ludlow Mines and data included in 2008 in Annual Report for Mineral Resources and Ore Reserves Estimates, Argonaut Mine); IMERYYS 427326, attached as **Exhibit 99** (core logs); IMERYYS 427419, attached as **Exhibit 100** (core drill log, includes serpentinite); IMERYYS 436951, attached as **Exhibit 101** (mine aerial pictures and ore description sheets); IMERYYS 427428, attached as **Exhibit 102** (core drill logs for south end of Argonaut mine); IMERYYS 418940, attached as **Exhibit 103** (memo with Argonaut Geology Maps attached).

³⁹⁵ Examples include Pltf_IMERYYS_00057875, attached as **Exhibit 104** (Downey Ex. 12, Memo re Cyprus Ore Reserves); Hopkins Exhibit 28, attached as **Exhibit 3** (chart of Samples with asbestos); IMERYYS 441340, attached as **Exhibit 98** (2008 Annual Report for Mineral Resources and Ore Reserves Estimates, Argonaut Mine); IMERYYS 501902, attached as **Exhibit 105** (Geology of and Product Applications for the Argonaut Talc Mine, Ludlow, Vermont); IMERYYS 238270, attached as **Exhibit 106** (1992 Interoffice Memo re Hamm Mine Core Drilling fibrous amphiboles observed); IMERYYS 418940, attached as **Exhibit 103** (Mineralogy Analysis of Vermont includes report on Tremolite asbestos in Vermont talc); IMERYYS 425354, attached as **Exhibit 107** (Cyprus Ore Reserve Evaluation, Preliminary Summary by R.C. Munro noting fibrous actinolite and fibrous tremolite in J&J mines); IMERYYS 427291, attached as **Exhibit 108** (North American Mines, Northeastern Ore Bodies, Master Plan, notes actinolite zones); IMERYYS 427326, attached as **Exhibit 103** (Argonaut Core Logs); IMERYYS 435992, attached as **Exhibit 109** (Hamm Mine Drill log showing fibrous tremolite); IMERYYS 436000, attached as **Exhibit 110** (Hamm Mine Drill Log showing fibrous actinolite); JNJ 000245002, attached as **Exhibit 111** (Hammondsville Geology and Ore Reserves, showing fibrous talc).

³⁹⁶ See **Exhibit 93**, Krekeler Dep. at 195:22–196:4, 200:3014.

Defendants cite two fibrous talc results, one potentially from the Gouverneur Mine³⁹⁷ and the other potentially from the Gassett Mine, as samples not from their mines or used to produce industrial talc. Even assuming these samples were erroneously included (something Plaintiffs do not concede), 39 out of 41 positive tests for fibrous talc remain valid and uncontested. This perceived mistake does not undermine the credibility and relevance of the other positive samples.³⁹⁸

Finally, both Drs. Krekeler and Cook describe asbestiform and non-asbestiform minerals in their reports.³⁹⁹ While Defendants highlight talc test results only listing “tremolite” without specifying its form (asbestiform or fibrous), other results describe the fibers and identify asbestiform. In Dr. Cook’s report, he notes before the asbestos chart that it includes “serpentine asbestos (chrysotile), amphibole asbestos, or potentially asbestiform amphiboles.” Anything “potentially asbestiform” is a matter for the jury and can be attacked on cross-examination.⁴⁰⁰

³⁹⁷ The documents used by Drs. Cook and Krekeler do not identify the talc as from the Gouverneur Mine. *See* JNJ 000238826, attached as **Exhibit 112** and JNJ 000248023, attached as **Exhibit 113**. Instead, J&J had to take Dr. Cook through multiple documents to try to prove this. Cook Dep. 388:21–393:20.

³⁹⁸ Defendants similarly point to samples that may have come from the Red Hill Mine and the Frostbite Mine. Again, even assuming these two instances are mistakes (which Plaintiffs do not concede), there are still over 100 positive results left in the chart showing asbestos results that Defendants do not challenge.

³⁹⁹ *See* **Exhibit 94**, Krekeler Report at 4; **Exhibit 96**, Cook Report at 4.

⁴⁰⁰ *See Daubert*, 509 U.S. at 596 (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.”).

Both experts' reports provide clear examples of asbestos, including chrysotile, asbestos fibers, fibrous minerals, and other descriptors.⁴⁰¹

CONCLUSION

For these reasons, the Court should deny J&J's Motion to Exclude Plaintiffs' Experts' Asbestos-Related Opinions.

Respectfully submitted,

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⁴⁰¹ See generally **Exhibit 96**, Cook Report; **Exhibit 94**, Krekeler Report.

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